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10 MAR 2004

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Glaxo Group Limited
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Patents ADP number *(if you know it)*

If the applicant is a corporate body, give the country/state of its incorporation

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4735870003

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An Inhaler

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# AN INHALER

## FIELD OF THE INVENTION

The present invention relates to an inhaler from which a medicament formulation is dispensable for inhalation by a user through a dispensing outlet of the inhaler. The invention also relates to a closure for closing the dispensing outlet and to an accessory for an inhaler.

The invention is particularly, but not exclusively, concerned with a pressurised metered dose inhaler (hereinafter referred to as a "pMDI"). The invention does, however, embrace other inhaler types, for example a dry powder inhaler (DPI), as will be appreciated by the reader skilled in the inhaler art.

## BACKGROUND OF THE INVENTION

pMDIs are well known in the art of inhalation devices. It is therefore not necessary to describe the construction and operation of a pMDI other than in bare essentials.

A pMDI comprises a canister unit and a housing. The housing is generally tubular, although this is not essential, and generally formed of a plastics material, for instance by moulding. The canister unit comprises an open-ended canister, typically made from a metal such as aluminium. The open end of the canister is sealingly capped by a metering valve assembly. The valve assembly includes a hollow dispensing member or valve stem which projects from the outlet or business end of the canister. The dispensing member is mounted for sliding movement relative to the canister between an extended position, to which the dispensing member is biased by a biasing mechanism in the valve assembly, and a depressed position.

In use, the sealed canister contains a pressurised medicinal aerosol formulation. The formulation comprises the medicament and a fluid propellant, and optionally one or more excipients and/or adjuvants. The medicament is typically in solution or suspension in the formulation. The propellant is typically a CFC-free propellant, suitably a liquid propellant, and may for example be HFA-134a or HFA-227.

Movement of the dispensing member from the extended position to the depressed position results in a metered dose of the aerosol formulation being dispensed from the canister through the dispensing member.

The housing comprises an internal passageway having an open end. The canister unit is slidable into the internal passageway through the open end with the canister unit being inserted valve assembly first into the internal passageway. A stem block, which receives the dispensing member of the canister when the canister unit is received in the housing in a "rest position", has a passageway with an inlet end for receiving the dispensing member and an outlet end, which faces a dispensing outlet of the housing, typically a mouthpiece or a nasal nozzle. The stem block holds the dispensing member stationary whereby depression of the canister unit from its rest position further into the housing to an "actuated position" causes the dispensing member to be displaced from the extended position to the depressed position relative to the canister. A metered dose of the aerosol formulation will thereby be dispensed out of the dispensing outlet of the housing via the internal passageway of the stem block.

In use, a patient in need of a metered dose of the medicinal aerosol formulation concurrently inhales on the dispensing outlet and depresses the canister unit from the rest position to the actuated position. The inspiratory airflow produced by the patient entrains the metered dose of the medicinal aerosol formulation into the patient's respiratory tract.

Inhalers are commonly provided with a dust cap that covers the dispensing outlet when the inhaler is not in use. The dust cap, when applied, prevents foreign material from entering the housing. This prevents the user from inhaling dust or lint, for example, that might otherwise accumulate in the housing. This is of particular importance where the user suffers from asthma or other respiratory conditions, in which the inhalation of foreign material may cause severe irritation.

Developments to pMDIs have included the provision of actuation indicators or dose counters therefor. Such a dose counter is described in PCT Patent Application Nos. WO-A-9856444 and WO-A-2004/001664 to Glaxo Group Limited. The pMDI canister unit may comprise the dose counter, which is fixably secured on the valve assembly end of the canister and includes a display which denotes the number of metered doses of the medicament formulation dispensed from, or remaining in, the canister. The display of the dose counter is visible to the patient through a window provided in the housing. The display may be presented by a plurality of indicator wheels rotatably mounted on a common axle, each wheel having numerals from '0' to '9' displayed in series around the circumference.

pMDI devices, however, are susceptible to unintentional actuation, particularly whilst in transit, for example shipment between the manufacturer and distributor. During such transit, such devices and their packaging are often subjected to impacts and sudden movements. Such forces can actuate the pMDI, causing doses of the formulation to be dispensed. When the pMDI includes a dose counter, rough handling in transit can cause the value displayed to the user by the counter to increase or decrease so that it is not consistent with the number of doses that have been dispensed by, or remain in, the pMDI. It is wasteful to dispense unwanted doses of the medicament, and potentially very dangerous for a

dose counter to indicate to the user that more doses remain in the canister than are actually present.

It is therefore desirable to provide a pMDI that is adapted to prevent unintentional actuation. It is also desirable to provide a pMDI with a dose counter, which is adapted to prevent miscounting actuations in the event of an impact.

A multiple-dose DPI with means of preventing unintentional actuation is marketed under the trademark Easyhaler (RTM), the basic inhaler construction being illustrated in WO-A-01/87391 (Orion Corporation). The Easyhaler (RTM) inhaler dispenses a powdered medicament when a dosing member is moved, relative to the body of the inhaler, towards a metering drum. This movement causes the drum to rotate, dispensing a single metered dose of the powdered medicament from a powder reservoir at an inhaler mouthpiece for entrainment in the inhalation airflow of a user inhaling thereat, and driving a dose counting mechanism. The inhaler also comprises a small hole through the body of the inhaler, situated above the mouthpiece. A cap is provided, to cover the mouthpiece when not in use, comprising a prong that protrudes through the hole and into the body of the inhaler when the cap is engaged by the mouthpiece. The presence of the prong inside the body of the inhaler restricts the motion of the dosing member in the direction of the drum, preventing the user from dispensing powder by pressing down on the dosing member while the cap is engaged.

There are, however, a number of disadvantages with the Easyhaler (RTM) inhaler. Should moisture enter the inhaler, the powder will agglomerate to form lumps that cannot enter the metering drum, thus affecting the dosage. Also, the interior surface of the mouthpiece is likely to become moist during use, causing the powdered medicament to stick to its interior surface.

Both DPIs and pMDIs mix a medicament with an air stream that is drawn through the device by the user's inhalation and the profile of the inhalation airflow within the housing of the inhaler is therefore important to product performance, for instance the fine particle mass (fpm) or respirable fraction of the emitted dose, as will be well understood by the skilled reader in the inhaler art. Providing a hole in the housing, as in the Easyhaler (RTM) device, alters the inhalation airflow profile through the device. Therefore, if an existing inhaler design is adapted to include a prong and hole arrangement, it would require re-testing for regulatory approval. This re-testing delays production and involves additional expense.

Consequently, it would be advantageous to provide a means for preventing accidental actuation of the inhaler without altering the inhalation airflow profile through the housing.

Another problem with the prior art Easyhaler (RTM) inhaler is that an adapted cap, provided with a prong, can only be used with inhalers that have been specially provided with a hole above the mouthpiece. The effect of this is that the cap is not reverse-compatible with previously manufactured housings and that the manufacture of the housing needs to be updated.

Some prior art inhalers comprise a strap that is used to secure the dust cap to the housing. This is particularly so of inhalers produced for the US market, where dust caps are required to be attached to the housing. Prior art straps commonly comprise an otherwise rigid plastic strip that can be flexed only at fold-lines provided close to points of attachment to the back of the housing and the dust cap, located at opposite ends of the strap. The roof of the dust cap comprises only a narrow lip and the sides cut away accordingly. In applying the dust cap, the user brings the strap along the

bottom of the housing, using the flexibility in the fold lines, and forces the lip over the roof of the dispensing outlet to engage it.

There are a number of problems with this strap. The first is that the lip of the dust cap requires the application of some force to engage it with the housing. Consequently, the dust cap may be difficult for people with weak fingers, for example the arthritic, to apply and remove. A second problem is that continual folding weakens the fold lines in the strap, which may break after a large number of folding actions.

An additional problem is present in those inhalers that comprise a prong attached to the dust cap. In order to enter the housing, the prong must be inserted in a particular orientation. The prior art strap and cap arrangements, discussed above, require the cap to be rotated, about a fold line, into position when it is applied. Accordingly, if the cap is to comprise a prong which must engage, for example, a hole in the housing, the sweeping motion of the prong as the cap rotates would present a problem.

It is therefore desirable to provide an inhaler with means of attaching a dust cap to the dispensing outlet that, whilst being secure when attached, is easy to apply and remove and does not limit the use of a prong, or similar restricting means, to prevent inadvertent actuation of the inhaler.

## SUMMARY OF THE INVENTION

One aspect of the present invention provides an inhaler for use with a container unit containing a medicament formulation to be dispensed, comprising a housing in which the container unit is relatively movable thereto to cause dispensing of a dose, preferably a metered dose, of the medicament formulation from the container unit for inhalation by a user through a dispensing outlet of the housing; a closure positionable to close the dispensing outlet; and a restricting member, provided on the closure,

movable between a first position which enables relative movement between the container unit and the housing for dispensing of the dose of the medicament formulation, and a second position in which the restricting member restricts relative movement between the container unit and the housing such that dispensing of the dose of the medicament formulation is prevented; wherein when the closure is positioned to close the dispensing outlet, the restricting member enters the housing through the dispensing outlet to be disposed in its second position.

This aspect of the invention, and others herein disclosed, is particularly advantageous since a prior art housing may be used. This reverse-compatibility is advantageous for the user, who can fit a closure (e.g. a dust cap) with a restricting member to an existing inhaler that he already owns, to the manufacturer, who is not required to change his manufacturing process for the housing, and also for the marketer, who will not need to seek new regulatory approval for an adapted housing.

In an embodiment of the invention, such as one hereinafter to be described, the container unit is a pressurised canister unit, optionally including a dose counter, for instance mounted at the leading end of the canister unit.

In an embodiment of the invention, such as one hereinafter to be described, the restricting member is configured as a clip that engages a surface of the housing and/or container unit, suitably the stem block and/or a step in the housing. This is advantageous since it secures the closure to the housing whilst the inhaler is not in use. Moreover, it secures the restricting member in its second position. In an embodiment of the invention, such as one hereinafter to be described, the clip configuration of the restricting member is such that, if the container unit is moved in its dispensing direction relative to the housing, it causes the gripping force of

the restricting member to increase ensuring that the closure is not ejected and dispensing does not occur.

In another aspect of the invention there is provided an inhaler comprising a housing having a dispensing outlet and a closure for closing the dispensing outlet which comprises an extendible connector part for connecting the closure to the housing.

Attaching the closure to the housing is a regulatory requirement in the United States and is in any case beneficial since it prevents loss of the closure or swallowing of it by the user. A particular advantage of an extensible connector (e.g. a strap) is that it reduces the force required to engage and disengage the closure. This is particularly important since many users of inhalers are elderly or infirm and may have weak fingers.

Optionally, the closure may comprise a restricting member. The presence of a restricting member is in itself desirable, as discussed above, and the connector comprised by the present invention is particularly suited to use with closures that comprise a restricting member and that must therefore be spaced sufficiently in front of the housing dispensing outlet that the restricting member can be correctly orientated before the cap is engaged.

In another possible embodiment, the restricting member is attached to the connector.

In an embodiment of the invention, such as one hereinafter to be described, the connector is telescopic and may comprise a first component attached to the housing and a second component attached to the closure, wherein the components are slidingly movable relative to each other between a contracted position, wherein the closure closes the dispensing outlet, and an extended position, wherein the closure is spaced from the

dispensing outlet. The two components may be connected using a pin on one component that is held captive within a slot in the other component. At least one of the components may comprise hinging means, for example a fold line. Additionally, raised edges may be provided on one of the components, to substantially prevent relative rotational movement of the components.

In another possible embodiment, the connector may be a strap, and this strap may be made of a flexible and elastically stretchable material, for example knitted elastic, and is stretchable between a contracted state, wherein the closure can be engaged by the dispensing outlet, and an extended state, wherein the closure can be disengaged from the dispensing outlet.

In another possible embodiment, the connector comprises a sliding hinge joining the closure to the housing such that the closure and the housing are capable of relative movement between a first position, wherein the closure closes the dispensing outlet, and a second position, wherein the closure is spaced from the dispensing outlet such that access to the dispensing outlet is substantially unobstructed by the dust cap. This sliding hinge may, in a possible further embodiment, comprise first and second pins located on opposing sides of the dispensing end and first and second slots located on first and second opposing elongated sides of the closure, wherein the pins are captive within in the slots but capable of rotational and sliding movement within them.

In further possible embodiments, the inhaler may be a pMDI and the medicinal formulation may be a medicinal aerosol formulation.

Other aspects and features of the present invention are set forth in the claims appended hereto. Each aspect of the invention may incorporate

one or more of the other aspects of the invention or one or more features from the other aspects of the invention.

Further aspects and features of the invention are set forth in the non-limiting exemplary embodiments of the invention which will now be described with reference to the accompanying Figures of drawings.

## BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 shows a pMDI, having a dust cap comprising a restricting member, that is provided with a telescopic strap according to an embodiment of the present invention.

FIGURES 2A-2D illustrate the action of disengaging the dust cap of the embodiment shown in FIGURE 1.

FIGURES 3A-3F are various views of a pMDI according to another embodiment of the present invention.

FIGURES 4A and 4B show another embodiment of the present invention, wherein a dust cap is provided with elongated sides and is attached to a pMDI by slidable hinges.

FIGURE 5 shows a prior art strap for attaching a dust cap to the housing of a pMDI usable in the implementation of the invention.

FIGURE 6 shows a further embodiment of the present invention, wherein a dust cap is provided with a restricting member that comprises a pair of arms, configured as a clip to engage a step in the base of the housing of a pMDI.

FIGURES 6A-6E are respectively perspective, plan, cross-sectional, side and front views of the dust cap in FIGURE 6.

FIGURE 6F is a schematic, fragmentary, part sectional view of the dust cap and canister unit of the pMDI of FIGURE 6 assembled to the housing showing how the restricting member is positioned in the housing relative to the canister unit.

FIGURES 7A and 7B show yet another embodiment of the present invention, having a dust cap secured to the housing of a pMDI by a strap and a restricting member attached to the strap and capable of entering the housing through a hole in its base.

FIGURES 8A and 8B show a yet further embodiment of the present invention wherein a restricting member is inserted between a canister unit and the inner surface of the housing of a pMDI, substantially preventing relative movement therebetween.

FIGURES 9A and 9B show a further embodiment of the invention in which a restricting member is mounted on the trailing end of the canister unit of a pMDI.

FIGURES 10A and 10B show an embodiment of the present invention having a restricting member inserted between a canister unit and the housing of a pMDI, through a display window in the housing.

FIGURES 11A and 11B show yet another embodiment of the invention in which a restricting member is adhesively secured to the canister unit and the housing of a pMDI.

FIGURES 12A and 12B show an alternative of the embodiment of FIGURES 11A and 11B.

FIGURES 13A and 13B show an embodiment of the invention in which the restricting member is adhesively secured to the canister unit of a pMDI through a window in the housing.

FIGURES 14A and 14B show a further embodiment of the invention in which a restricting member is mounted on the trailing end of the canister unit of a pMDI.

## DETAILED DESCRIPTION OF THE EXEMPLARY EMBODIMENTS

In the following description like reference numerals have been used to indicate like parts in the different embodiments of the invention. Each embodiment is comprised in a pMDI which is hand-held and hand-operable.

FIGURES 1 and 2 show a pMDI according to a first embodiment of the present invention. In this embodiment, the pMDI is based on a pMDI known in the prior art, as described in the 'Background of the Invention' section *supra*, although the present invention is not limited to the exact form of such an arrangement.

The pMDI comprises a canister unit 14 and a housing 1 in which the canister unit 14 is slidable along its longitudinal axis L-L. The housing 1 is generally tubular and of L-shape having an axial section 1a and a transverse section 1b configured as a mouthpiece 3. In the use orientation of the pMDI shown in FIGURES 1 and 2, the housing 1 has an upper open end 4a in the axial section 1a, through which the canister unit 14 is reversibly slidable into the housing 1, and a lower open end 4b in the mouthpiece 3.

The canister unit 14 comprises a pressurised canister 14a having a metering valve (see reference numeral 50, FIGURE 6F) at its leading or

business end and a dose counter module (see reference numeral 14b, FIGURE 6) mounted on the leading (valve) end of the canister 14a. The dose counter module is as described and shown in WO-A-2004/001664 *supra*, the content of which is incorporated herein by reference in its entirety. The canister 14a contains a pressurised medicinal aerosol formulation, as known in the art and mentioned briefly hereinabove.

In use, a patient in need of a metered dose of the medicinal aerosol formulation places his or her lips on the mouthpiece 3 of the housing 1 and then concurrently inhales and, with their finger(s), depresses the canister unit 14 into the housing 1 (arrow F) to cause the metering valve to release a metered dose of the medicinal formulation from the canister unit 14 for entrainment in the inspiratory airflow produced by the patient for deposition in their lungs. The depression of the canister unit 14 into the housing 1 also results in the dose counter module recording the release of the dose and showing the number of metered doses left in the canister 14a.

A dust cap 5 is attached to the housing 1 by a telescopic strap 2 comprising first 7 and second 8 components. The first component 7 is attached at one end to the housing 1 by a hinge 9 and has a pin 11 at the opposite end to the housing 1. One end of the second component 8 is attached to the dust cap 5 by a second hinge 10. The second component 8 comprises a linear slot 12, in which the pin 11 of the first component 7 is held captive. As shown in FIGURES 2A-2D, although captive within the slot 12, the pin 11 is free to move along its length and thus the two components 7, 8 are capable of relative sliding motion along the length of the slot 12 between a contracted position, with a maximum overlap of the components 7, 8, and an extended position, with a minimum overlap of the components 7, 8.

As illustrated in FIGURES 2A-D, to remove the dust cap 5, the user pulls it away from the mouthpiece 3 with sufficient force to overcome a

snap-fit connection therebetween (not shown), thereby extending the telescopic strap 2 to its extended position. Then, the telescopic strap 2 is pivoted at hinges 9, 10, swinging the dust cap 5 clear of the mouthpiece 3 so that it does not obstruct the mouthpiece 3 so that the pMDI is able to be actuated as described above.

To reapply the dust cap 5, the user moves the telescopic strap 2 about the hinges 9, 10 so that the dust cap 5 is repositioned in front of the mouthpiece 3 and is then pushed towards it, compressing the telescopic strap 2 towards its contracted position. The snap-fit connection reconnects.

Side walls 4 may be provided to substantially prevent relative rotational movement of the components 7, 8 about the pin 11.

From an inside surface of the dust cap 5 there projects a restricting member 6 for restricting movement of the canister unit 14 in the housing 1 when the cap 5 is mounted on the mouthpiece 3 such that inadvertent firing and counting cannot take place.

Referring to FIGURE 1, the restricting member 6 is in the form of an arm or prong structure comprising a pair of spaced apart arms 6a, 6b. When the dust cap 5 is positioned on the mouthpiece 3, as shown in FIGURE 2A, the arms 6a, 6b extend into the housing 1 through the lower open end 4b to straddle the stem block (see reference numeral 18, FIGURE 6) for the valve stem to sit underneath the dose counter module at the leading end of the canister unit 14 (as shown in FIGURES 3F and 6F). The arms 6a, 6b prevent the canister unit 14 being depressed sufficiently in the housing 1 to either (a) cause the dose counter module to record a dose release event, or (b) cause the metering valve to open for release of a metered dose of the medicament formulation. The arms 6a, 6b thus prevent inadvertent counting and firing when the dust cap 5 is mounted on

the mouthpiece 3, which is nearly all the time as the dust cap 5 is only removed from the mouthpiece 3 when the patient needs a dose of the medicament formulation.

Such inadvertent counting and firing might occur, for example, if the arms 6a, 6b were not present, during shipping of the pMDI from the manufacturer to the distributor, or when the pMDI is in a patient's pocket or handbag, or even as a result of a person fiddling/playing with the pMDI. Wastage of the medicinal formulation is therefore reduced.

Moreover, as a safeguard, the dose counter module is adapted to record release of a metered dose from the canister 14a after depression of the canister unit 14 into the housing by a distance which is less than that required for opening of the metering valve. In other words, the dose counter module is set-up for a 'count-not-fire' event, rather than a 'fire-not-count' event, if the pMDI is not used properly. This is because it is preferable for the dose counter display to show that there are less doses left than are actually available than vice-versa. However, it is not easy to depress the canister unit 14 only far enough to cause a 'count-not-fire' event.

In any event, the arms 6a, 6b prevent 'count-not-fire' events occurring while the dust cap 5 is on.

By having the restricting member 6 extend through the mouthpiece 3, no changes need to be made to the housing 1 to accommodate it. Thus, the dust cap 5 can be used with existing pMDI housings. Moreover, the profile of the inhalation airflow through the housing 1, which flows into the housing 1 through the upper open end 4a and out of the housing 1 through the lower open end 4b, is unaffected by the provision of the restricting member, since it requires no change to the housing and is removed from the housing prior to use of the pMDI. Consequently, the pharmaceutical

performance of the pMDI is unaffected by the provision of the restricting member 6 avoiding the need to obtain new regulatory approval for an existing pMDI product using the new dust cap 5.

It will be appreciated that providing the cap 5 with the telescopic strap 2 provides the cap 5 with the ability to be manoeuvred onto and off the mouthpiece 3 despite it carrying the restricting member 6.

In this embodiment and the others hereinafter to be described, the dust cap 5 and the strap 2 are moulded from polypropylene (PP), although, of course, other materials, in particular plastics materials, and forming techniques, may be used. When the strap 2 is moulded, the hinges 9, 10 are so-called "living hinges". Moreover, the cap 5 is integrally formed with the restricting member 6 and the second component 8 of the strap. The first strap component 7 may be formed separately and then assembled to the second strap component 8. Alternatively, the strap 2 may be integrally formed with the first strap component 7.

FIGURES 3A-F show a pMDI in accordance with a second embodiment of the invention which corresponds to the first embodiment *supra* in all respects bar some of the structure of the dust cap 5.

The dust cap 5 has a restricting member 6 in the form of an arm structure comprising a pair of arm members 6a, 6b. The free ends of each arm member 6a, 6b are configured as clips 6c, 6d which, when the cap 5 is mounted on the mouthpiece 3, clip to a step 20 (see also FIGURE 6) in the base surface of the housing 1 which supports the stem block (reference 18, FIGURE 6).

If the canister unit 14 is depressed into the housing 1 while the cap 5 is mounted on the mouthpiece 3, the leading end of the canister unit 14 will push down on the upper surfaces 6e, 6f of the arms 6a, 6b which, as

shown in FIGURE 3F, have a tapered or ramp profile. More particularly, when the cap 5 is located on the mouthpiece 3, as in FIGURE 3F, the upper surfaces 6e, 6f of the cap arms 6a, 6b taper upwardly in the outward or dispensing direction (arrow B). Thus, when the canister unit 14 is depressed into the housing 1 along its axis L-L (arrow A), its leading end abuts the upper surfaces 6e, 6f of the cap arms 6a, 6b tending to push the cap 5 outwardly (arrow B). However, this results in the clips 6c, 6d engaging the step 20 more firmly preventing ejection of the cap 5 and thus inadvertent counting and firing.

In the second embodiment the first component 7 of the telescopic strap 2 has a distal track member 7a with opposed side walls 4. At the distal end of the track member 7a the side walls 4 are bridged by a bridging element 4c. At the proximal end of the first component 7 there is a hinge member 7b which is secured to the housing 1. The track and hinge members 7a, 7b are hinged together by the hinge 9 whereby the track member 7a is hingable about the hinge member 7b.

As regards the second component 8 of the telescopic strap 2, this has a proximal slide member 8a which is linearly slidable in the track member 7a and guided in its linear stroke by the side walls 4. The slide member 8a has a stop element 8b at its proximal end which engages with the bridging element 4c to demark the extended position of the strap 2 and to keep the slide member 8a captive in the track member 7a. At the distal end of the second component 8 there is provided a hinge member 8c hinged to the slide member 8a through the hinge 10. The hinge member 8c of the second component 8 is carried by the dust cap 5.

In an alternative embodiment of the invention, not shown, the strap for the dust cap 5 is made from an elastic stretchable material, for example knitted elastic. In this embodiment, the strap can be elastically extended to permit the user to remove or reapply the dust cap 5 and its flexibility

allows the dust cap 5 to be easily positioned clear of the mouthpiece 3 whilst the pMDI is in use.

In a third embodiment of the invention, shown in FIGURES 4A and 4B, the dust cap 5 has elongated sides 13 which are disposable on opposed sides of the lateral section 1b of the housing 1. A pin 16 is provided on each side of the housing lateral section 1b. Each elongated side 13 of the dust cap 5 has a slot 15 along its length, which has closed ends. The slots 15 hold the pins 16 captive. The arrangement of the slots 15 and pins 16 secures the dust cap 5 to the housing 1, whilst permitting the dust cap 5 to be rotated about the common axis A-A of the pins 16 and moved towards and away from the mouthpiece 3 along the length of the slots 15.

To remove the dust cap 5, the user pulls it away from the mouthpiece 3, sliding the pins 16 within the slots 15. The user then rotates the dust cap 5 about the pins 16, swinging it below the housing 1 to prevent it obstructing the mouthpiece 3. The dust cap 5 is then reapplied by swinging it back into a position in front of the mouthpiece 3 and then sliding it back over the pins 16 until it engages the mouthpiece 3.

Referring to FIGURE 5, there is shown a pMDI with a dust cap 5 attached to the housing 1 using a prior art strap 2, having fold lines 9, 10 at each end to permit the strap and dust cap 5 to be folded behind the housing when the pMDI is in use. The sides and roof of the dust cap 5 may be cut away, leaving a lip 17 with which the dust cap 5 engages the mouthpiece 3, as described in the 'Background of the Invention' section *supra*. In an embodiment of the invention, the dust cap 5 of this prior art arrangement is provided with a restricting member, such as illustrated and described herein. However, this embodiment is disadvantageous compared to others for the reasons discussed above in the 'Background of the Invention' section.

FIGURE 6 is a schematic view of a pMDI in accordance with a fourth embodiment of the present invention which corresponds closely to the second embodiment described with reference to FIGURES 3A-F. In FIGURE 6 a scrap detail of the lower part of the housing 1 is shown to reveal the base surface in which the step 20 is formed and from which the stem block 18 for the valve stem (118, FIGURE 6F) projects upwardly. As further shown, the stem block 18 has a spray orifice 18a oriented towards the lower open end 4b in the mouthpiece 3 whereby the metered dose fired from the canister unit 14 on depression thereof into the housing 1 is directed out of the mouthpiece 3.

FIGURE 6 further shows the dose counter module 14b mounted on the leading (valve) end of the canister unit 14. The dose counter module 14b has a display window 14c which displays the number of metered doses of the medicament formulation left in the canister 14a, as described in WO-A-2004/001664 *supra*. The housing 1 has a cut-out or window 1c through which the patient can see the dose counter display 14c.

As detailed in WO-A-2004/001664, the dose counter module 14b has a counting mechanism which is driven through a rack-and-pinion mechanism. FIGURE 6 shows the rack 30 which also projects upwardly from the housing base surface. The rack is slidingly received in an aperture (not shown) in the leading face of the dose counter module 14b. When the canister unit 14 is depressed into the housing 1 for opening of the metering valve, the rack drives a pinion (not shown) in the dose counter module 14b and the rotary movement of the pinion causes the counting mechanism to decrement the number displayed in the dose counter window 14c by dose counter wheels (not shown).

In the fourth embodiment of the invention the pMDI has a dust cap 5 for detachably engaging the mouthpiece 3 which corresponds to that shown in FIGURES 3A-3F other than that it does not include a connector for

connecting the cap 5 to the housing 1. Different views of the dust cap 5 of the fourth embodiment are shown in FIGURES 6A-6E.

As shown in FIGURES 6A-6E, the arms 6a, 6b forming the restricting member 6 are interconnected along part of their length by a strengthening rib 6h, in order to increase their strength and rigidity. As discussed previously, the configuration of the free ends of the arms 6a, 6b as clips 6c, 6d which engage the step 20 is advantageous, since if the canister unit 14 is moved downwards in the housing 1, for instance if the pMDI is dropped, it pushes the arms 6a, 6b towards the step 20, so as to increase the gripping force of the clips to ensure that the dust cap 5 and restricting member 6 do not eject from the mouthpiece 3.

FIGURE 6F shows schematically how the restricting member 6 prevents actuation of the pMDI in the same way described for the second embodiment with reference to FIGURE 3F. Specifically, the arms 6a, 6b sit underneath the dose counter module 14b to prevent it moving towards the base 32 of the housing 1 the required distance for the valve stem 118 to be depressed into the canister 14a for release of the metered dose nor for the rack 30 to drive the pinion for decrementing the dose counter display 14c.

As further shown in FIGURE 6F, a clip 19a is provided on the dust cap 5 to engage a slot 19b on the outer surface of the mouthpiece 3 to provide additional retention of the dust cap 5 on the housing 1. However, none of the clips 6c, 6d, 19a prevent the dust cap 5 from being fairly easily removed from the housing 1 by a user.

The restricting member 6 is asymmetrically arranged in the dust cap 5, inasmuch as being located closer to the cap bottom than to the cap top (FIGURES 6A, 6C, 6D, 6F). If the dust cap 5 is mounted on the mouthpiece 3 in an inverted orientation, then the canister unit 14 may not be able to be inserted properly into the housing 1. Accordingly, the dust cap 5 may be

provided with indicia indicating the correct orientation of the cap 5, for example by providing indicia on the cap outer surface, for instance on its front face 5a.

The restricting member 6 is also provided with lateral alignment ribs 21 to prevent it from being inserted at more than a prescribed angle to the mouthpiece 3, whereupon one of the arms 6a, 6b might be inserted into a hollow 18b in the stem block 18 or be otherwise obstructed by the components of the pMDI. In other words, the alignment ribs 21 ensure that the dust cap 5 is mounted on the mouthpiece 3 so that the arms 6a, 6b straddle the stem block 18 with the clips 6c, 6d clipping into engagement with the step 20.

In an alternative embodiment of the invention, not shown, the clips 6c, 6d of the restricting member 6 could be reconfigured such that they clip onto the stem block 18 to retain the cap 5 in place for blocking movement of the canister unit 14 in the housing 1 in the firing direction.

FIGURES 7A and 7B show a pMDI in accordance with a fifth embodiment of the present invention in which a strap 25 is provided to attach the dust cap 5 to the housing 1 and a restricting member 24 is mounted on said strap. The strap 25 and restricting member 24 are positioned so that when the dust cap 5 is in a position in which it engages the mouthpiece 3, the restricting member 24 protrudes into the housing 1 through a hole 28 in the base 32 of the housing 1 to act as a prop for the canister unit 14. The length of the restricting member 24 is such that it prevents the canister unit 14 from being depressed to within a predetermined distance of the base 32 of the housing 1 to prevent actuation (firing and counting) of the pMDI. When the dust cap 5 is removed, the strap 25 moves away from the base 32 of the housing 1 and the restricting member 24 exits the hole 28 thereby enabling the canister unit 14 to be actuated.

FIGURES 8A and 8B show a pMDI in accordance with a sixth embodiment of the present invention in which a disposable restricting member 22 is removably inserted between the housing 1 and the canister unit 14. The restricting member 22 is made from an elastically compressible material, such as a foam, and is inserted at the upper open end 4a of the housing 1 with the canister unit 14 positioned in a rest position in the housing 1 from which it needs to be depressed into the housing for operation of the dose counter module 14b and the metering valve. The restricting member 22 acts as wedge between the canister unit 14 and the inner surface of the housing 1 and also tilts the canister unit 14 in the direction of arrow C into engagement with the housing inner surface. As the restricting member 22 is elastically compressible, it applies an outward lateral holding force on the inner surface of the housing 1 and the outer surface of the canister unit 14. Depression of the canister unit 14 into the housing 1 for actuation of the metering valve and the dose counter module 14b is thereby prevented.

Unlike the previous embodiments hereinabove described with reference to the FIGURES of drawings, the restricting member 22 in the sixth embodiment also prevents or inhibits retraction of the canister unit 14 from the housing 1 until the restricting member 22 is removed.

As represented in FIGURE 8B, the restricting member 22 is removed and discarded prior to the first actuation of the pMDI. It is particularly useful for preventing inadvertent actuation of the pMDI before the pMDI is given to the patient, e.g. through knocks when being shipped or transported from the manufacturer to the distributor and then to the clinic.

The restricting member 22 may be adhesive, to further increase the holding force it applies to the canister unit 14 and the housing inner surface.

The wedge concept for the restricting member may also be realised in other shapes and configurations for the restricting member.

FIGURES 9A and 9B show a seventh embodiment of the invention in which an annular restricting member 22 is slid over the canister 14a to form a tight fit thereon, e.g. an interference or press fit. This is achieved by the restricting member 22 having an aperture 22a of transverse dimension which is no greater than that of the canister 14a and, where the aperture 22a is of a transverse dimension less than that of the canister 14a, being radially expandable when slid onto the canister 14a. The restricting member 22 prevents depression of the canister unit 14 into the housing far enough for actuation of the metering valve and the dose counter module 14b by abutting with the lip of the upper open end 4a of the housing 1. In this embodiment, the restricting member 22 is in the form of a foam collar, although other elastic or resilient materials would work equally well.

FIGURES 10A and 10B show an eighth embodiment of the present invention wherein the pMDI is packaged with a restricting member 23 partially inserted into the housing 1 through the display window 1c. The user removes and discards the restricting member 23 from the housing 1 prior to the first actuation of the pMDI. When in place, the restricting member 23 separates the canister unit 14 and the base 32 of the housing 1. This prevents the canister unit 14 from moving sufficiently far inside the housing 1 for actuation of the metering valve and the dose counter module 14b. As shown in FIGURE 10B, the user removes the restricting member 23 by pulling on the portion that remains exterior to the housing 1. With the restricting member 23 removed, the canister unit 14 is free to move inside the housing 1 for actuation of the pMDI.

FIGURES 11A and 11B show a ninth embodiment of the invention in which an adhesive restricting member 33 adheres to the canister unit 14 through the housing display window 1c. The restricting member 33 is an adhesive tape that also adheres to the housing 1. Securing the canister unit 14 and the housing 1 together in this manner prevents relative movement between the two such that the canister unit 14 can be neither actuated (firing and counting) nor removed. Prior to first use, the patient peels the restricting member 33 away and discards it, as shown in FIGURE 11B.

FIGURES 12A and 12B show a tenth embodiment of the invention having an adhesive restricting member 34 in the form of a double-sided adhesive tape which is folded over the lip of the upper open end 4a of the pMDI housing to define an inner tape section 34a, which is adhered to the outer surface of the canister unit 14, and an outer tape section 34b, which is adhered to the outer surface of the housing 1. The inner tape section 34a may also be adhered to the inner surface of the housing 1. As will be appreciated, this configuration prevents depression of the canister unit 14 into the housing 1 for actuation (firing and counting) thereof. The restricting member 34 is removed and discarded by the patient prior to first use of the pMDI.

FIGURES 13A and 13B show an eleventh embodiment of the invention which is similar to the ninth embodiment in having a restricting member 35 that is adhered to the canister unit 14 through the housing display window 1c. In this instance, however, the restricting member 35 is not adhered to the housing 1. The restricting member 35 is an adhesive pad of not negligible thickness, preferably at least the thickness of the housing 1 around the display window 1c, which is aligned adjacent the edge of the display window 1c. The canister unit 14 is prevented from moving downwards and upwards in the housing 1 for actuation and removal thereof by the blocking action of the restricting member 35 against the edge of the

display window 1c. Again, the restricting member 35 is removed and discarded prior to the first actuation of the pMDI, as indicated in FIGURE 13B.

FIGURES 14A and 14B show a twelfth embodiment of the invention in which a restricting member 60 in the form of a cap is press-fitted to both the top of the canister unit 14 and the outer surface of the housing 1 adjacent its upper open end 4a. The cap may be formed by vacuum forming. Relative movement of the canister unit 14 in the housing 1 is thus prevented insofar as stopping actuation (firing and counting) and removal of the canister unit 14.

Thus, a wide variety of different embodiments of the invention have been described which all restrict relative movement of the canister unit 14 in the housing the required distance for the dose counter module 14b to be actuated and a dose of the medicament formulation to be dispensed. Some of the embodiments also restrict the relative movement such that the canister unit 14 is unable to be removed from the housing 1 until the restricting member is removed or disengaged.

For the avoidance of doubt, it will be appreciated that the present invention is equally applicable where the canister unit 14 does not include the dose counter module 14b. That is to say, the canister unit 14 may simply be the pressurised canister 14a with its valve. Alternatively, some other accessory or cap or module may be mounted to the leading end of the canister 14a in place of the dose counter module.

The restricting members of FIGURES 8 to 14 are particularly useful for preventing inadvertent actuation of the pMDI before the pMDI is given to the patient, e.g. through knocks, jolts or jars when being shipped or transported from the manufacturer to the distributor and then to the clinic.

The medicament contained in the canister unit 14 may for the treatment of mild, moderate or severe acute or chronic symptoms or for prophylactic treatment. The medicament is suitably for treating respiratory diseases, e.g. asthma, chronic obstructive pulmonary disease (COPD), although may be for other therapeutic indications, e.g. treating rhinitis.

Appropriate therapeutic agents or medicaments may thus be selected from, for example, analgesics, e.g., codeine, dihydromorphine, ergotamine, fentanyl or morphine; anginal preparations, e.g., diltiazem; antiallergics, e.g., cromoglycate (e.g. as the sodium salt), ketotifen or nedocromil (e.g. as the sodium salt); antiinfectives e.g., cephalosporins, penicillins, streptomycin, sulphonamides, tetracyclines and pentamidine; antihistamines, e.g., methapyrilene; anti- inflammatories, e.g., beclomethasone (e.g. as the dipropionate ester), fluticasone (e.g. as the propionate ester), flunisolide, budesonide, rofleponide, mometasone (e.g. as the furoate ester), ciclesonide, triamcinolone (e.g. as the acetonide), 6α, 9α-difluoro-11β-hydroxy-16α-methyl-3-oxo-17α-propionyloxy-androsta-1,4-diene -17β-carbothioic acid S-(2-oxo-tetrahydro-furan-3-yl) ester or 6α, 9α-Difluoro-17α-[(2-furanylcarbonyl)oxy]-11β-hydroxy-16α-methyl-3-oxo-androsta-1,4-diene-17β-carbothioic acid S-fluoromethyl ester; antitussives, e.g., noscapine; bronchodilators, e.g., albuterol (e.g. as free base or sulphate), salmeterol (e.g. as xinafoate), ephedrine, adrenaline, fenoterol (e.g. as hydrobromide), formoterol (e.g. as fumarate), isoprenaline, metaproterenol, phenylephrine, phenylpropanolamine, pirbuterol (e.g. as acetate), reproterol (e.g. as hydrochloride), rimiterol, terbutaline (e.g. as sulphate), isoetharine, tulobuterol or 4-hydroxy-7-[2-[[2-[[3-(2-phenylethoxy) propyl] sulfonyl] ethyl] amino]ethyl-2(3H) benzo-thiazolone; PDE4 inhibitors e.g. cilomilast or roflumilast; leukotriene antagonists e.g. montelukast, pranlukast and zafirlukast; [adenosine 2a agonists, e.g. 2R,3R,4S,5R)-2-[6-Amino-2-(1S-hydroxymethyl-2-phenyl-ethylamino)-purin-9-yl]-5 -(2-ethyl-2H-tetrazol-5-yl)-tetrahydro-furan-3,4-diol (e.g. as maleate)]; [α4 integrin inhibitors e.g.

(2S)-3-[4-({[4-(aminocarbonyl)-1-piperidinyl] carbonyl}oxy)phenyl]-2-[((2S)-4-methyl-2-{[2-(2-ethylphenoxy)acetyl]amino}pentanoyl)amino] propanoic acid (e.g as free acid or potassium salt)], diuretics, e.g., amiloride; anticholinergics, e.g., ipratropium (e.g. as bromide), tiotropium, atropine or oxitropium; hormones, e.g., cortisone, hydrocortisone or prednisolone; xanthines, e.g., aminophylline, choline theophyllinate, lysine theophyllinate or theophylline; therapeutic proteins and peptides, e.g., insulin or glucagons. It will be clear to a person skilled in the art that, where appropriate, the medicaments may be used in the form of salts, (e.g., as alkali metal or amine salts or as acid addition salts) or as esters (e.g., lower alkyl esters) or as solvates (e.g., hydrates) to optimise the activity and/or stability of the medicament and/or to minimise the solubility of the medicament in the propellant.

Preferably, the medicament is an anti-inflammatory compound for the treatment of inflammatory disorders or diseases such as asthma and rhinitis.

Preferably, the medicament is formulated in a hydrofluoroalkane propellant, such as HFA-134a or HFA-227 or a combination thereof.

Preferably, the medicament is an anti-inflammatory steroid, such as a corticosteroid, for instance fluticasone, e.g. as the propionate ester, or a long acting beta agonist (LABA), such as salmeterol, e.g. as the xinafoate salt, or a combination thereof.

Preferred medicaments are salmeterol, salbutamol, albuterol, fluticasone and beclomethasone and salts, esters or solvates thereof, for instance fluticasone propionate, albuterol sulphate, salmeterol xinafoate and beclomethasone diproprionate.

The medicament may also be a glucocorticoid compound, which has anti-inflammatory properties. One suitable glucocorticoid compound has the chemical name: 6α, 9α-Difluoro-17α-(1-oxopropoxy)-11β-hydroxy-16α-methyl-3 - oxo-androsta-1,4-diene-17β-carbothioic acid *S*-fluoromethyl ester (fluticasone propionate). Another suitable glucocorticoid compound has the chemical name: 6α, 9α-difluoro-17α-[(2-furanylcarbonyl)oxy]-11β-hydroxy-16α-methyl-3-oxo-androsta -1,4-diene-17β-carbothioic acid *S*-fluoromethyl ester. A further suitable glucocorticoid compound has the chemical name: 6α,9α-Difluoro-11β-hydroxy-16α-methyl-17α-[(4-methyl-1,3-thiazole-5-carbonyl)oxy]-3-oxo-androsta-1,4-diene - 17β -carbothioic acid *S*-fluoromethyl ester.

Other suitable anti-inflammatory compounds include NSAIDs e.g. PDE4 inhibitors, leukotriene antagonists, iNOS inhibitors, tryptase and elastase inhibitors, beta-2 integrin antagonists and adenosine 2a agonists.

The medicaments may be delivered in combinations. As an example, there may be provided salbutamol (e.g. as the free base of the sulphate salt) or salmeterol (e.g. as the xinafoate salt) in combination with an anti-inflammatory steroid, such as beclomethasone (e.g. as an ester, preferably dipropionate) or fluticasone (e.g. as an ester, preferably propionate).

It will be understood that the present invention has been described above by way of example only and that the above description should not be taken to impose any limitation on the scope of the claims. Specifically, although the present invention has been described with reference to a pMDI, the invention is not limited to this form of inhaler. The scope of the invention is defined by the appended claims.

CLAIMS

1. An inhaler for use with a container unit containing a medicament formulation to be dispensed, comprising:-

a housing in which the container unit is relatively movable thereto to cause dispensing of a dose, preferably a metered dose, of the medicament formulation from the container unit for inhalation by a user through a dispensing outlet of the housing;

a closure positionable to close the dispensing outlet; and

a restricting member, provided on the closure, movable between a first position which enables relative movement between the container unit and the housing for dispensing of the dose of the medicament formulation, and a second position in which the restricting member restricts relative movement between the container unit and the housing such that dispensing of the dose of the medicament formulation is prevented;

wherein when the closure is positioned to close the dispensing outlet, the restricting member enters the housing through the dispensing outlet to be disposed in its second position.

2. The inhaler of claim 1, wherein in use the dose of the medicament formulation is dispensed from the container unit when the container unit moves relative to the housing in a first direction and wherein the restricting member in its second position restricts movement of the container unit in the first direction.

3. The inhaler of claim 1 or 2, wherein in its second position the restricting member restricts relative movement between the container unit and the housing through physical engagement of the restricting member with the container unit.

4. The inhaler of claim 1, 2 or 3, wherein the restricting member, in its second position, is disposed in front of a leading end of the container unit.

5. The inhaler of any one of the preceding claims, wherein the housing has an axis along which the container unit is movable relative to the housing to dispense the dose of the medicament formulation and the restricting member, in its second position, extends laterally to the axis to restrict said relative movement.

6. The inhaler of any preceding claim, wherein the restricting member is configured as an arm structure.

7. The inhaler of any preceding claim, wherein the restricting member is configured as a clip which, in its second position, clips to the housing and/or the container unit to retain the restricting member in its second position.

8. The inhaler of any preceding claim, wherein the container unit is a dispensing container unit having first and second parts which are movable relative to one another, said relative movement causing dispensing of the dose of the medicament formulation from the dispensing container unit, and wherein the housing has a support for supporting the first part of the dispensing container unit in a stationary position relative to the housing so that, in use, the second part is able to move in the housing relative to the first part to dispense the dose of the medicament formulation, and wherein the restricting member, in its second position, restricts the movement of the second part relative to the first part to prevent dispensing of the dose.

9. The inhaler of claim 8, wherein one of the first and second parts is a dispensing outlet member of the dispensing container unit and the other part is a container member containing the medicament formulation.

10. The inhaler of claim 9, wherein the first part is the dispensing outlet member and the second part is the container member and wherein the

support is adapted in use to direct the output of the dispensing outlet member out of the housing through the dispensing outlet thereof.

11. The inhaler of claim 8, 9 or 10 which is a pressurised metered dose inhaler (pMDI) with the second part being a pressurised container member containing therein the medicament formulation under pressure and the first part being a valve stem of a metering valve for releasing a metered dose of the pressurised medicament formulation from the dispensing container unit upon relative movement between the pressurised container member and the valve stem.

12. The inhaler of any of claims 8 to 11, wherein the restricting member comprises a pair of arms that straddle the support when the restricting member is in the second position.

13. The inhaler of claims 11 and 12, wherein the support is a stem block for receiving the valve stem.

14. The inhaler of any one of claims 8 to 13 when appended to claim 7, wherein the clip detachably engages the support.

15. The inhaler of claim 7 or any claim appended thereto, wherein the clip detachably engages a step in the housing.

16. The inhaler of any one of claims 8 to 14 in combination with claim 15, wherein the step is in a surface of the housing on which the support is provided.

17. The inhaler of any one of the preceding claims, wherein the closure is movable between a closing position, engaged with the housing, in which it closes the dispensing outlet and places the restricting member in the

second position, and an opening position in which it opens the dispensing outlet and places the restricting member in its first position.

18. The inhaler of any one of the preceding claims, wherein the closure is detachably mountable on the housing.

19. The inhaler of claims 17 and 18, wherein in use the closure is moved from its closing position to its opening position by detaching the closure from the housing.

20. The inhaler of any one of the preceding claims in which the closure is releasably engageable with the dispensing outlet of the housing to close the dispensing outlet.

21. The inhaler of claims 17 and 20, wherein in use the closure is moved from its closing position to its opening position by disengaging the closure from the dispensing outlet.

22. The inhaler of any one of the preceding claims further having an indicator for indicating dispensing from the container unit.

23. The inhaler of claim 22 in which the indicator has a visual display for indicating dispensing from the container unit.

24. The inhaler of claim 23 in which the indicator is adapted to update the display in response to movement of the container unit relative to the housing.

25. The inhaler of claim 24, wherein the indicator is adapted to update the display in response to relative movement of the container unit to the housing by a distance which is less than that required for dispensing of the dose of the medicament formulation from the container unit and wherein

the restricting member in its second position restricts the relative movement of the container unit and the housing such as to prevent updating of the display.

26. The inhaler of any one of the preceding claims provided with the container unit.

27. The inhaler of claim 26 in which the container unit further has a metering mechanism for dispensing a metered dose of the medicament formulation on movement of the container unit relative to the housing.

28. The inhaler of claim 26 or 27 when appended to any one of claims 22 to 25, wherein the indicator is comprised in the container unit.

29. The inhaler of claim 28, wherein the indicator is mounted on a container member of the container unit which contains the medicament formulation and suitably the restricting member, in its second position, co-operates with the indicator to restrict relative movement between the container unit and the housing.

30. The inhaler of claim 28 or 29 in which the indicator is mounted at the leading end of the container unit.

31. The inhaler of claim 28, 29 or 30 when appended to claim 8 in which the indicator is comprised in the second part of the container unit.

32. The inhaler of any one of the preceding claims, wherein the dispensing outlet of the housing is in a nozzle configured for insertion into a human or animal body orifice, for example a nostril or a mouth of a human or animal body.

33. The inhaler of any preceding claim further having a connector which connects the housing and the closure to one another.

34. The inhaler of claim 33, wherein the connector is extensible.

35. The inhaler of claim 33 or 34, wherein the connector is telescopic.

36. The inhaler of claim 34 or 35, wherein the connector comprises:-
a first component, attached to the housing; and
a second component, attached to the closure;
wherein the components are capable of relative movement, suitably sliding movement, between a contracted position, in which the closure closes the dispensing outlet, and an extended position, in which the closure is spaced from the dispensing outlet.

37. The inhaler of claim 36, wherein one of said components comprises a pin and the other comprises a slot, wherein the pin is captive within the slot and capable of movement within it.

38. The inhaler of claim 36 or 37, wherein at least one of the components comprises hinging means.

39. The inhaler of any one of claims 33 to 38, wherein the connector is a strap.

40. The inhaler of claims 34 and 39, wherein the strap is elastically stretchable between a contracted state, in which the closure is positionable to close the dispensing outlet, and an extended state, in which the closure is spaced remote from the dispensing outlet.

41. The inhaler of claim 33, wherein the connector comprises a sliding hinge joining the closure to the housing such that the closure and the

housing are capable of relative movement between a first position, in which the closure closes the dispensing outlet, and a second position, in which the closure is spaced from the dispensing outlet such that access thereto is substantially unobstructed thereby.

42. The inhaler of claim 41, wherein the sliding hinge comprises:-

first and second pins located on opposing sides of the dispensing outlet; and

first and second slots located on first and second opposing elongated sides of the closure,

wherein the pins are captive within the slots, but capable of rotational and sliding movement within them.

43. An inhaler comprising a housing having a dispensing outlet, and a closure for closing the dispensing outlet, wherein the closure comprises a connector part for connecting the closure to the housing characterised in that the connector part is extendible.

44. The inhaler of claim 43, wherein the connector part is telescopic.

45. The inhaler of claim 43 or 44, wherein the connector part comprises

a first component, attached to the housing; and

a second component, attached to the closure;

wherein the components are capable of relative movement, suitably sliding movement, between a contracted position, in which the closure closes the dispensing outlet, and an extended position, in which the closure is spaced remote from the dispensing outlet.

46. The inhaler of claim 45, wherein one of said components comprises a pin and the other comprises a slot, wherein the pin is captive within the slot and capable of movement within it.

47. The inhaler of claim 45 or 46, wherein at least one of the components comprises hinging means.

48. The inhaler of any one of claims 43 to 47, wherein the connector part is a strap.

49. The inhaler of claims 43 and 48, wherein the strap is elastically stretchable between a contracted state, in which the closure is positioned to close the dispensing outlet, and an extended state, in which the closure is positioned remote from the dispensing outlet.

50. The inhaler of claim 43, wherein the connector part comprises a sliding hinge joining the closure to the housing such that the closure and the housing are capable of relative movement between a first position, in which the closure closes the dispensing outlet, and a second position, in which the closure is spaced remote from the dispensing outlet such that access to the dispensing outlet is substantially unobstructed by the closure.

51. The inhaler of claim 50, wherein the sliding hinge comprises

first and second pins located on opposing sides of the dispensing outlet; and

first and second slots located on first and second opposing elongated sides of the closure,

wherein the pins are captive within the slots, but capable of rotational and sliding movement within them.

52. An inhaler comprising:-

a housing in which a medicament formulation is received and a dispensing member is relatively movable to cause dispensing of a dose, preferably a metered dose, of the medicament formulation for inhalation by a user through a dispensing outlet of the housing; and

a restricting member adapted to restrict relative movement between the dispensing member and the housing such that dispensing of the dose of the medicament formulation is prevented;

characterised in that the restricting member is fastened to the canister unit.

53. The inhaler of claim 52 in which the restricting member is further fastened to the housing so as to connect the dispensing member to the housing to restrict said relative movement.

54. The inhaler of claim 52 or 53 in which the restricting member is releasably fastened to the dispensing member and/or the housing.

55. The inhaler of any of claims 52 to 54 in which the restricting member is adhesively secured to the dispensing member and/or the housing.

56. The inhaler of any of claims 52 to 55 in which the restricting member is fastened to an end of the dispensing member which protrudes from the housing.

57. The inhaler of any of claims 52 to 56 in which the restricting member is adapted to abut the housing to restrict said relative movement.

58. The inhaler of claim 56 or claims 56 and 57 in which the restricting member is selected from the group consisting of a cap or collar mounted on the dispensing member end.

59. The inhaler of any of claims 52 to 55 in which the restricting member is disposed in an aperture in the housing, the aperture having an edge against which the restricting member is adapted to abut to restrict said relative movement.

60. The inhaler of any of claims 52 to 60 in which the restricting member is fastened to the dispensing member by an interference fit or a press fit.

61. The inhaler of any of claims 52 to 60 in which the restricting member is fastened to the dispensing member for movement therewith.

62. An inhaler comprising:-

a housing in which a medicament formulation is received and a dispensing member is relatively movable to cause dispensing of a dose, preferably a metered dose, of the medicament formulation for inhalation by a user through a dispensing outlet of the housing; and

a restricting member which is inserted between the dispensing member and the housing to restrict the relative movement therebetween such that dispensing of the dose of the medicament formulation is prevented.

63. The inhaler of claim 62, wherein the restricting member is a wedge between the dispensing member and the housing.

64. The inhaler of claim 62 or 63, wherein the restricting member is made from an elastically compressible material.

65. The inhaler of claim 64, wherein the restricting member is in a compressed state.

66. The inhaler of any of claims 62 to 65, wherein the restricting member is of a foam material.

67. The inhaler of any one of claims 62 to 66, wherein a portion of the restricting member projects from the housing to enable the restricting member to be pulled from the housing thereby enabling relative movement

between the dispensing member and the housing which causes the dose to be dispensed.

68. The inhaler of claim 67, wherein the restricting member projects from an opening in the housing.

69. The inhaler of any of claims 52 to 68 in which the dispensing member is movable along an axis of the housing, movement of the dispensing member in a first axial direction causing dispensing of the dose and movement in an opposed second axial direction removing the dispensing member from the housing, wherein the restricting member restricts movement of the dispensing member in the first and second axial directions.

70. The inhaler of any of claims 62 to 68 in which the dispensing member is movable relative to the housing along an axis to cause dispensing of the dose, wherein the restricting member is inserted between axially-oriented surfaces of the dispensing member and the housing.

71. An inhaler comprising:-

a housing in which a medicament formulation is received and a dispensing member is relatively movable along an axis of the housing, movement of the dispensing member in a first axial direction causing dispensing of a dose, preferably a metered dose, of the medicament formulation for inhalation by a user through a dispensing outlet of the housing, and movement in an opposed second axial direction removing the dispensing member from the housing; and

a restricting member which is positioned in the inhaler to restrict relative movement between the dispensing member and the housing along said axis such that dispensing of the dose of the medicament formulation is prevented and removal of the dispensing member from the housing is inhibited or prevented.

72. An inhaler comprising:-

a housing in which a medicament formulation is received and a dispensing member is relatively movable to cause dispensing of a dose, preferably a metered dose, of the medicament formulation for inhalation by a user through a dispensing outlet of the housing; and

a restricting member movable between a first position which enables relative movement between the dispensing member and the housing for dispensing of the dose of the medicament formulation, and a second position in which the restricting member restricts relative movement between the dispensing member and the housing such that dispensing of the dose of the medicament formulation is prevented;

characterised in that the restricting member enters the housing through the dispensing outlet to be disposed in its second position.

73. The inhaler of claim 72, wherein the restricting member is releasably attachable to the housing in its second position.

74. The inhaler of claim 72 or 73, wherein the restricting member is part of an accessory which is attachable to the housing.

75. The inhaler of claim 74, wherein the accessory is attachable to the dispensing outlet of the housing.

76. The inhaler of any of claims 52 to 75 in which the dispensing member is a container unit in which the medicament formulation is contained.

77. The inhaler of any of claims 1 to 76 which is a pMDI.

78. The inhaler of any preceding claim, wherein the medicament formulation is an inhalable formulation, for example an aerosol formulation.

79. An accessory for use with an inhaler which comprises a housing for receiving therein a medicament formulation and a dispensing member for relative movement therebetween which causes a dose of the medicament formulation to be dispensed for inhalation by a user through a dispensing outlet of the housing, the accessory adapted to be releasably attached to the inhaler in a use position and having a restricting member which, when the accessory is attached to the inhaler in its use position, extends into the housing through the dispensing outlet to restrict the relative movement between the housing and the dispensing member such that dispensing of the dose is prevented.

80. The accessory of claim 79 which is engaged with the housing in its use position.

81. The accessory of claim 79 or 80 which is engaged with the dispensing outlet in its use position.

82. The accessory of claim 79, 80 or 81 which is a closure for closing the dispensing outlet in the use position.

83. The accessory of any of claims 79 to 82, wherein the restricting member is an arm structure.

84. The accessory of claim 83, wherein the arm structure has a pair of spaced-apart arm members.

85. The accessory of any of claims 79 to 84, wherein the restricting member is configured as a clip for clipping to the housing and/or the dispensing member.

86. The accessory of claim 85 when appended to claim 83 or 84, wherein the arm structure has a distal end configured as a clip portion.

87. The accessory of claims 85 and 86, wherein the distal end of each arm member has a clip portion.

88. The accessory of any of claims 79 to 87 having a connector part for connecting the accessory to the housing whereby the accessory is movable between a non-use position and the use position while connected to the housing.

89. A closure for use with an inhaler which comprises a housing for receiving therein a medicament formulation for inhalation by a user through a dispensing outlet of the housing, the closure having a closing part for closing the dispensing outlet of the housing and a connector part for connecting the closure to the housing, the closing part being movable between a closing position, in which it closes the dispensing outlet, and an opening position, in which it opens the dispensing outlet, while the closure is connected to the housing by the connector part, characterised in that the connector part is extendible between a contracted state and an extended state to enable the closure part to move between its closing and opening positions, respectively.

90. The closure of claim 89, wherein the connector part is a strap.

91. The closure of claim 89 or 90, wherein the connector part is telescopic.

92. A connector for connecting an accessory to an inhaler housing in which a medicament formulation is received and in which a dispensing member is relatively movable to dispense a dose of the medicament formulation for inhalation by a user at a dispensing outlet of the housing,

wherein the connector comprises a restricting member adapted in use to restrict movement of the dispensing member relative to the housing to prevent the dose being dispensed.

93. The connector of claim 92, wherein the restricting member is insertable through an opening in the housing to a position in which it restricts the relative movement of the dispensing member to the housing.

94. The connector of claim 92 or 93 carrying the accessory which is engageable on the housing in a use position, the restricting member being positioned to restrict said relative movement when the accessory is in its use position.

95. The connector of claim 94, wherein the accessory is a closure which in its use position closes the dispensing outlet.

96. An inhaler substantially as hereinbefore described with reference to FIGURES 1 and 2A-D, or FIGURES 3A-F, or FIGURES 4A-B, or FIGURE 5, or FIGURES 6 and 6A-F, or FIGURES 7A-B, or FIGURES 8A-B, or FIGURES 9A-B, or FIGURES 10A-B, or FIGURES 11A-B, or FIGURES 12A-B, or FIGURES 13A-B, or FIGURES 14A-B of the accompanying drawings.

97. A closure for an inhaler substantially as hereinbefore described with reference to FIGURES 1 and 2A-D, or FIGURES 3A-F, or FIGURES 4A-B, or FIGURE 5, or FIGURES 6 and 6A-F, or FIGURES 7A-B of the accompanying drawings.

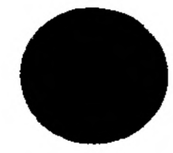
98. A connector for connecting an accessory to an inhaler housing substantially as hereinbefore described with reference to FIGURES 1 and 2A-D, or FIGURES 3A-F, or FIGURES 4A-B or FIGURES 7A-B of the accompanying drawings.

# AN INHALER

## Abstract

An inhaler is provided with a restricting member 6 to prevent unintentional actuation of the inhaler. Also provided is an inhaler with an extensible strap 2 joining a dust cap 5 to the housing 1 of an inhaler, the strap being particularly suited for use with inhalers that comprise a restricting member. The inhaler is useful, for example, in the treatment of asthma.

(FIG. 3E)



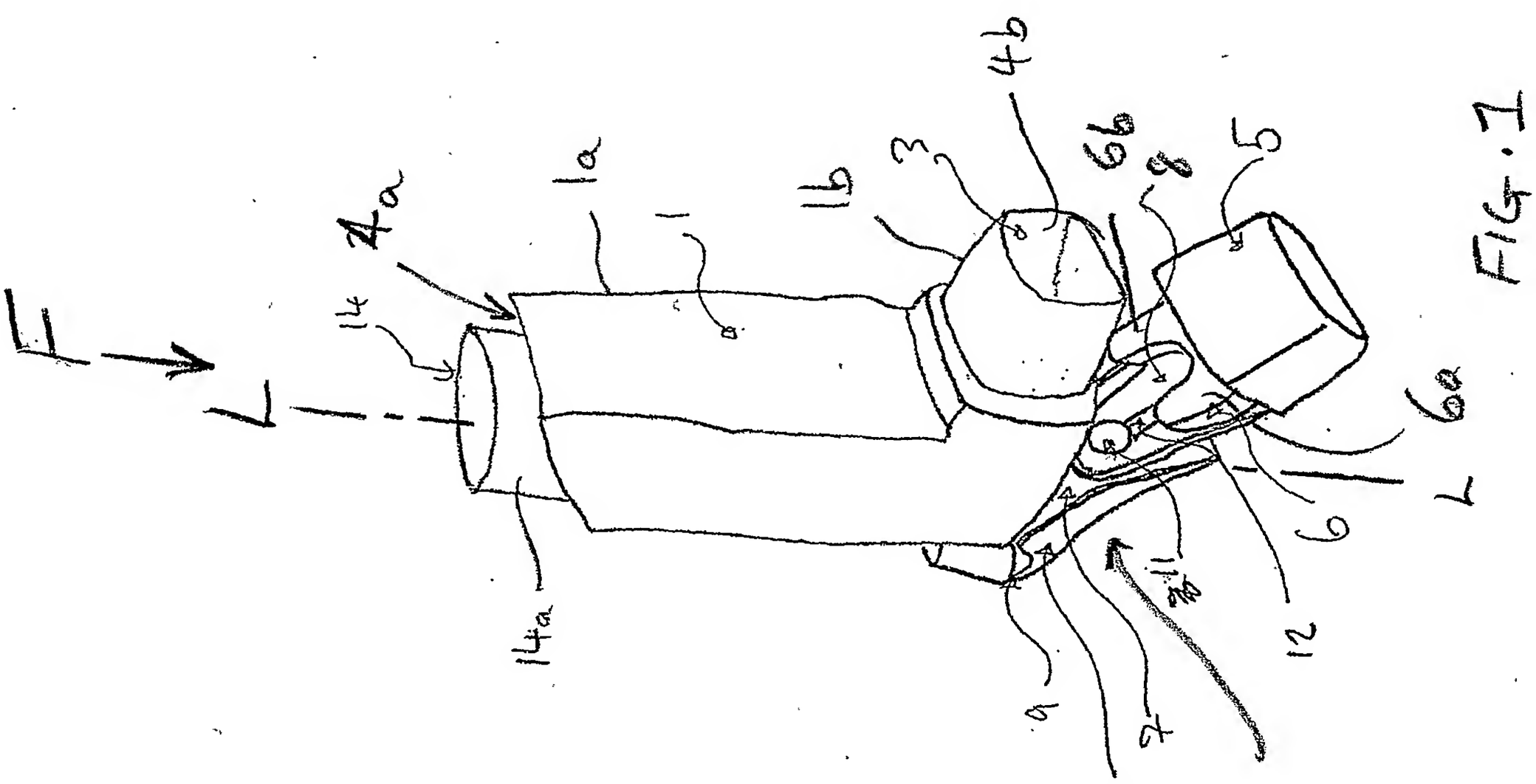



FIG. 7

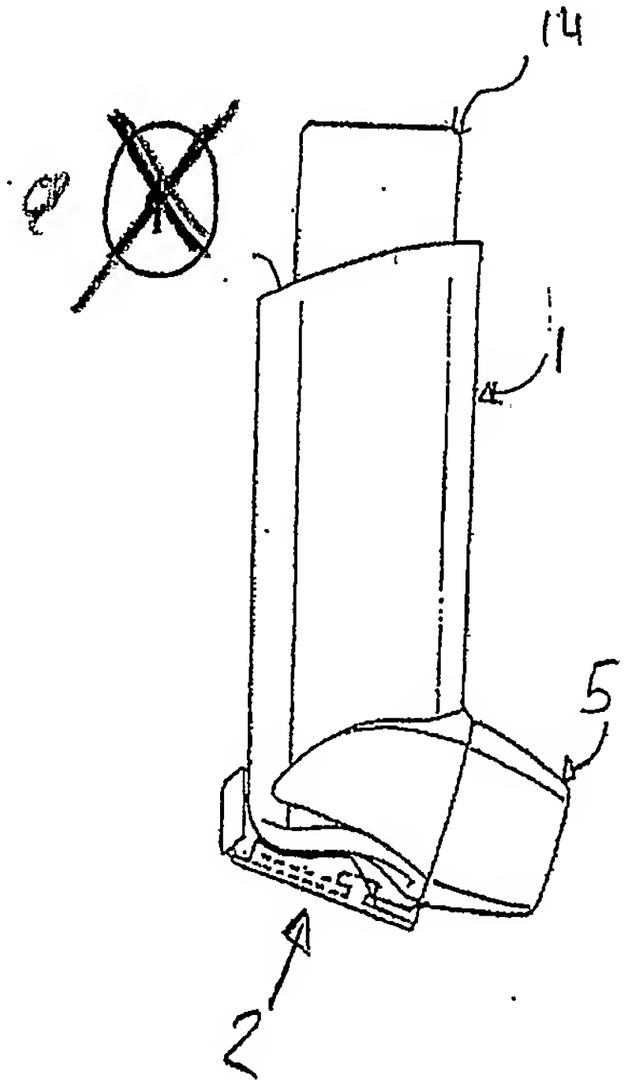



FIG. 2A

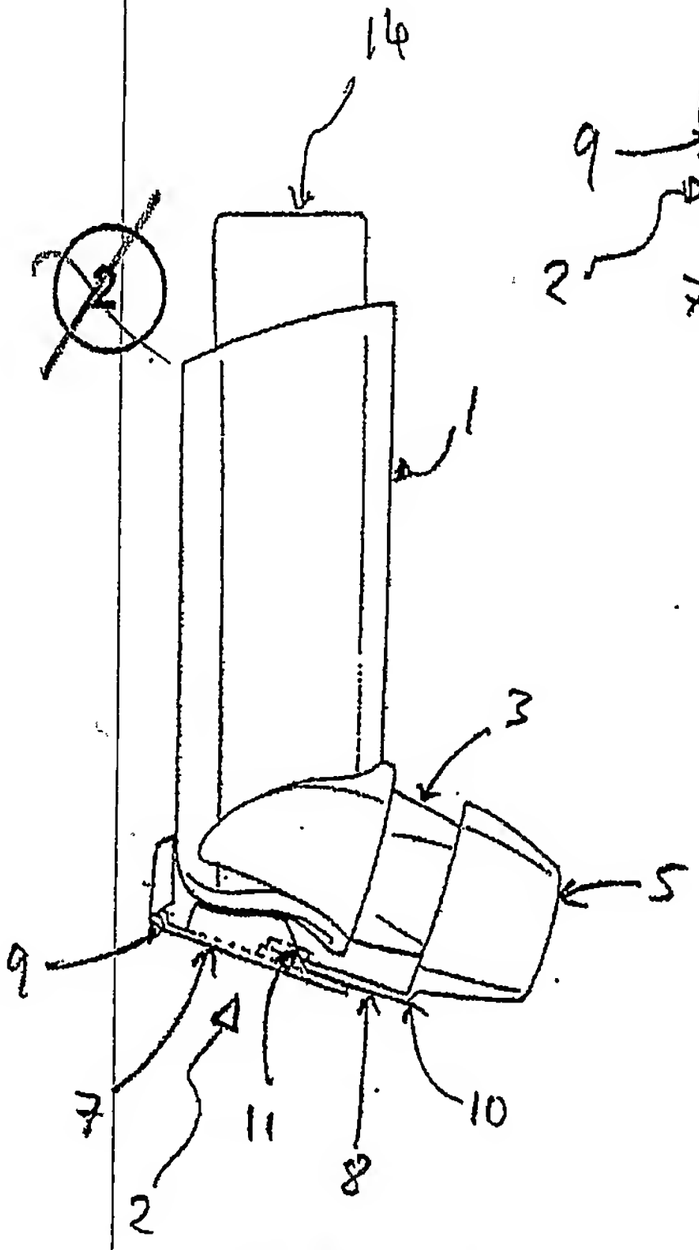



FIG. 2B

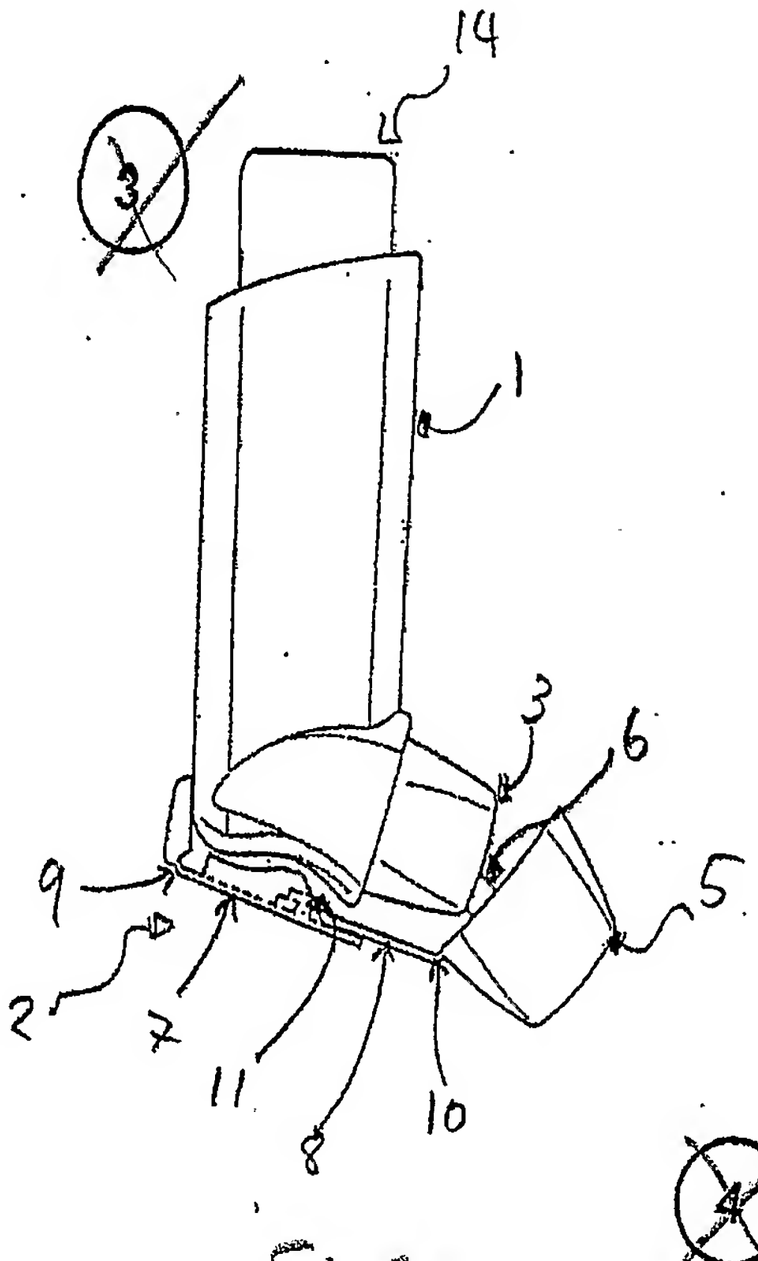



FIG. 2C

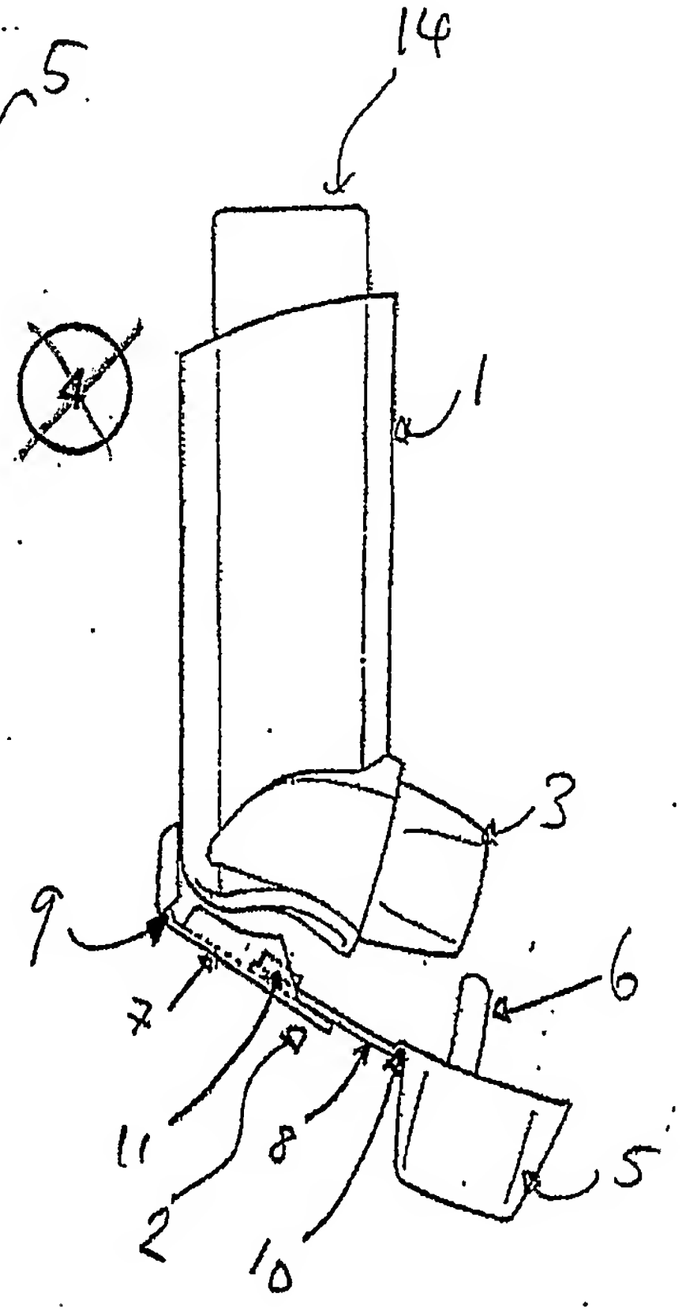



FIG. 2D

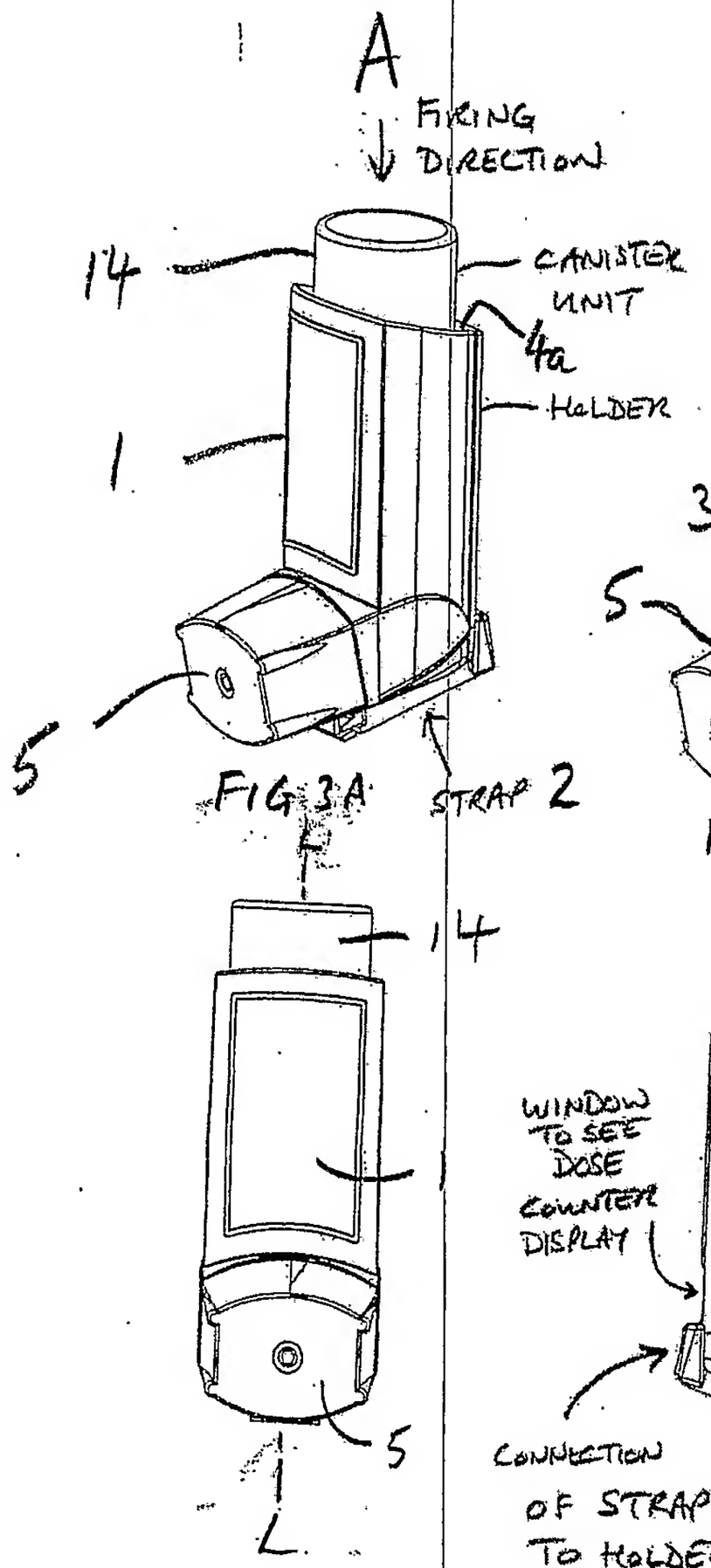



FIG 3A




FIG. 3B

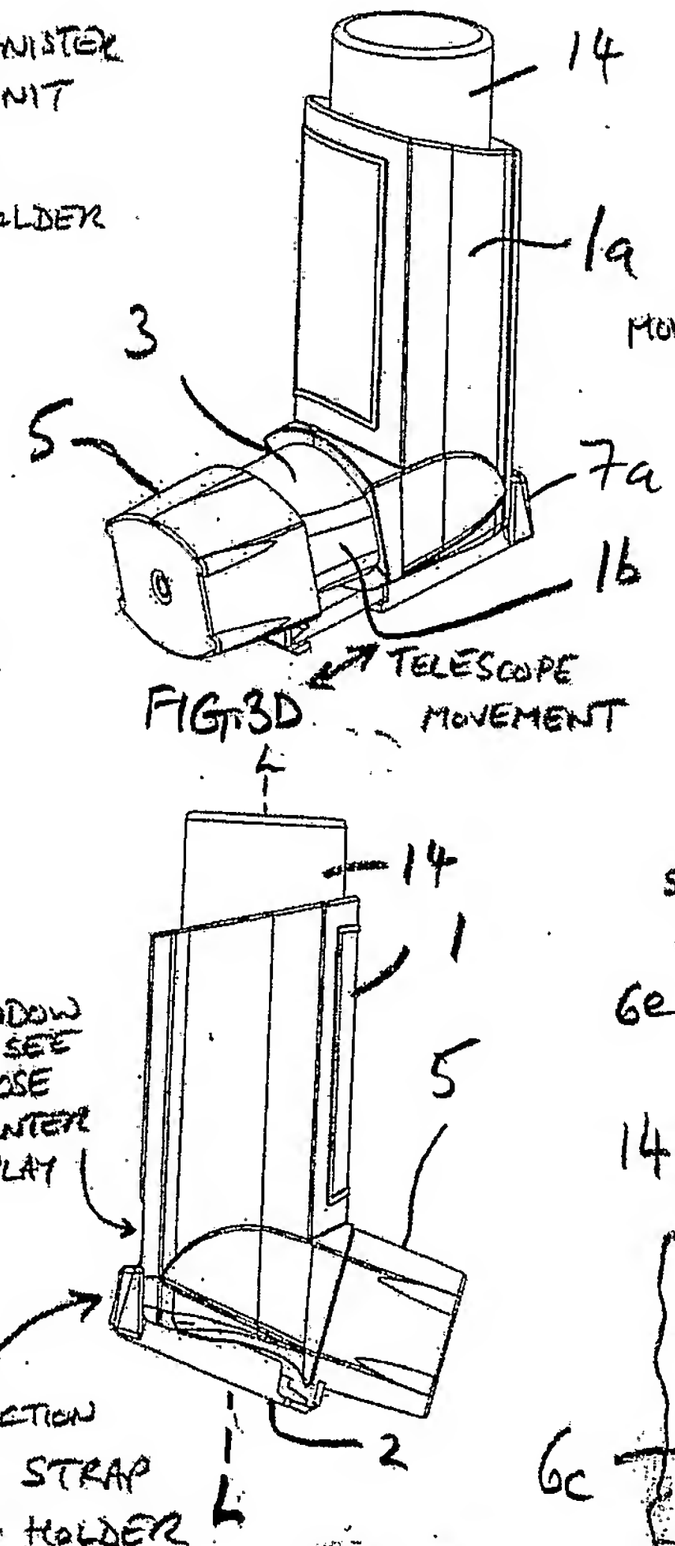



FIG. 3C

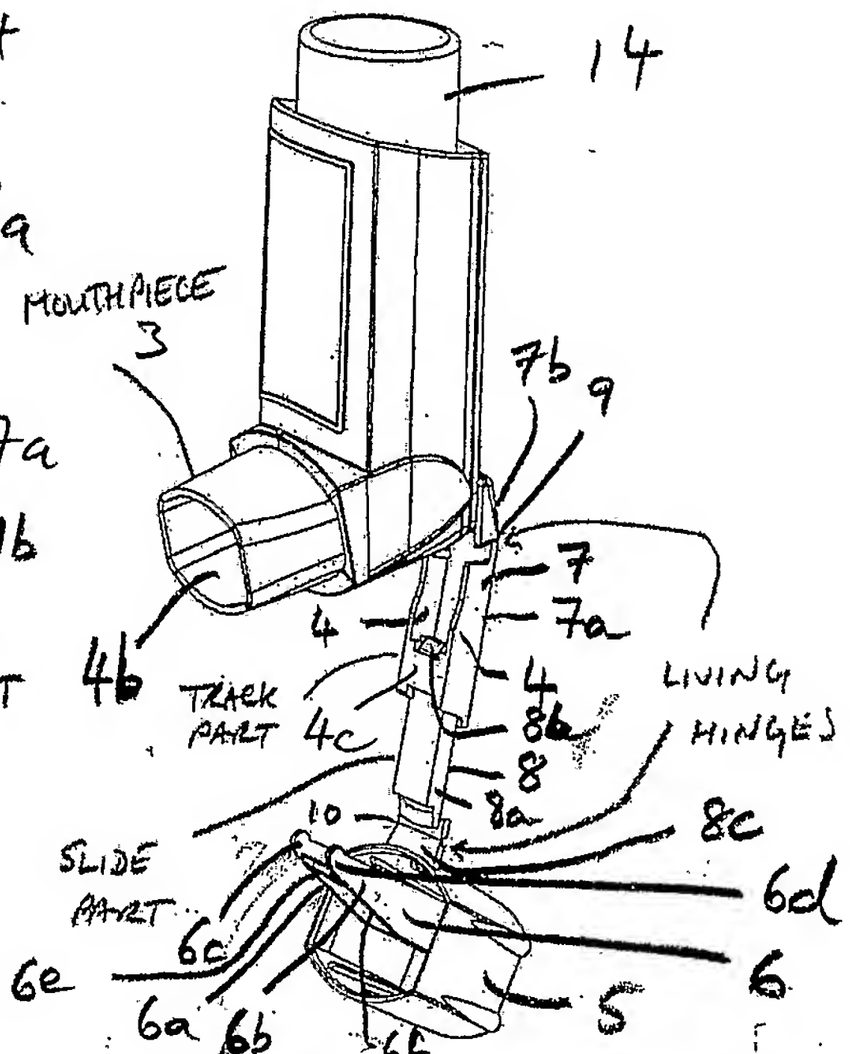



FIG. 3E

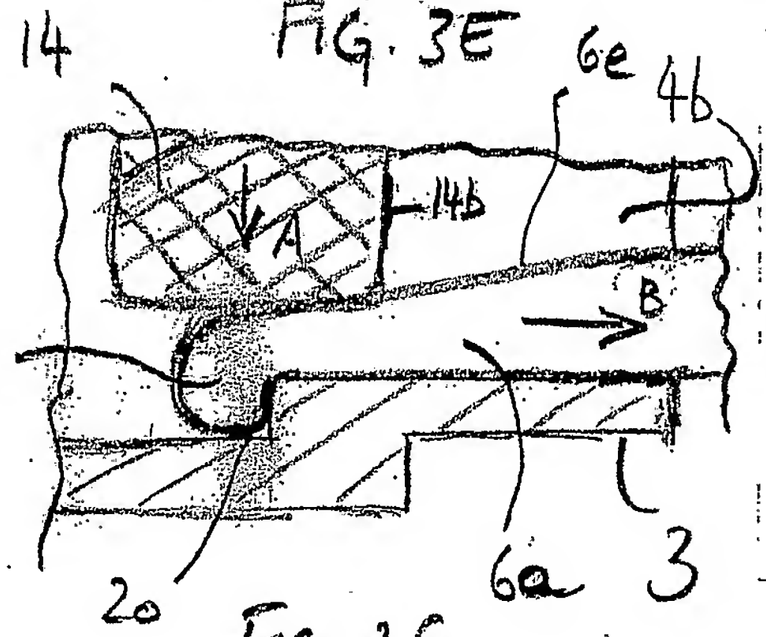



FIG. 3F

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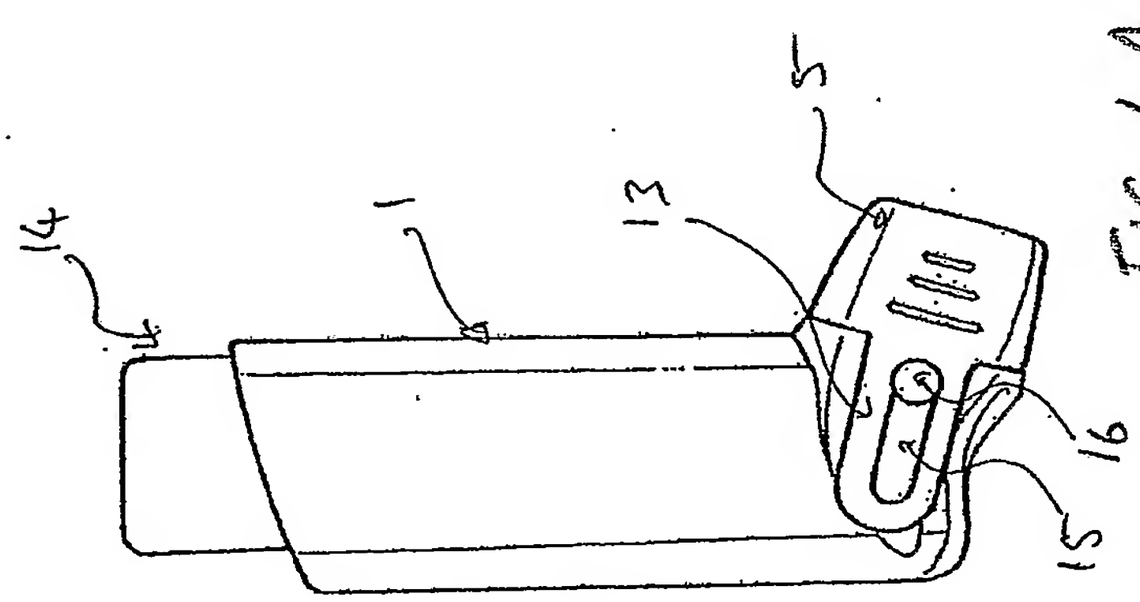


FIG. 4A

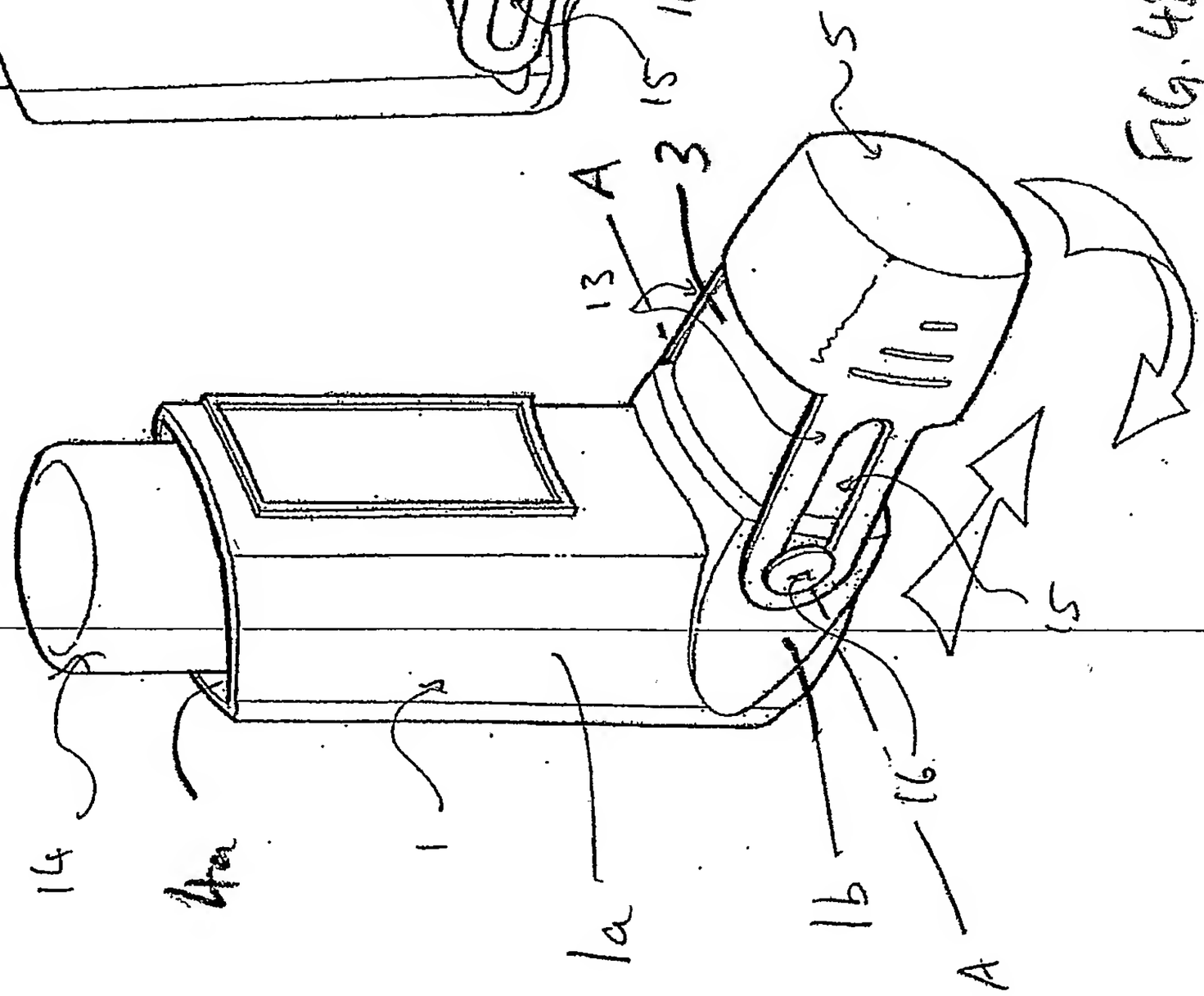


FIG. 4B

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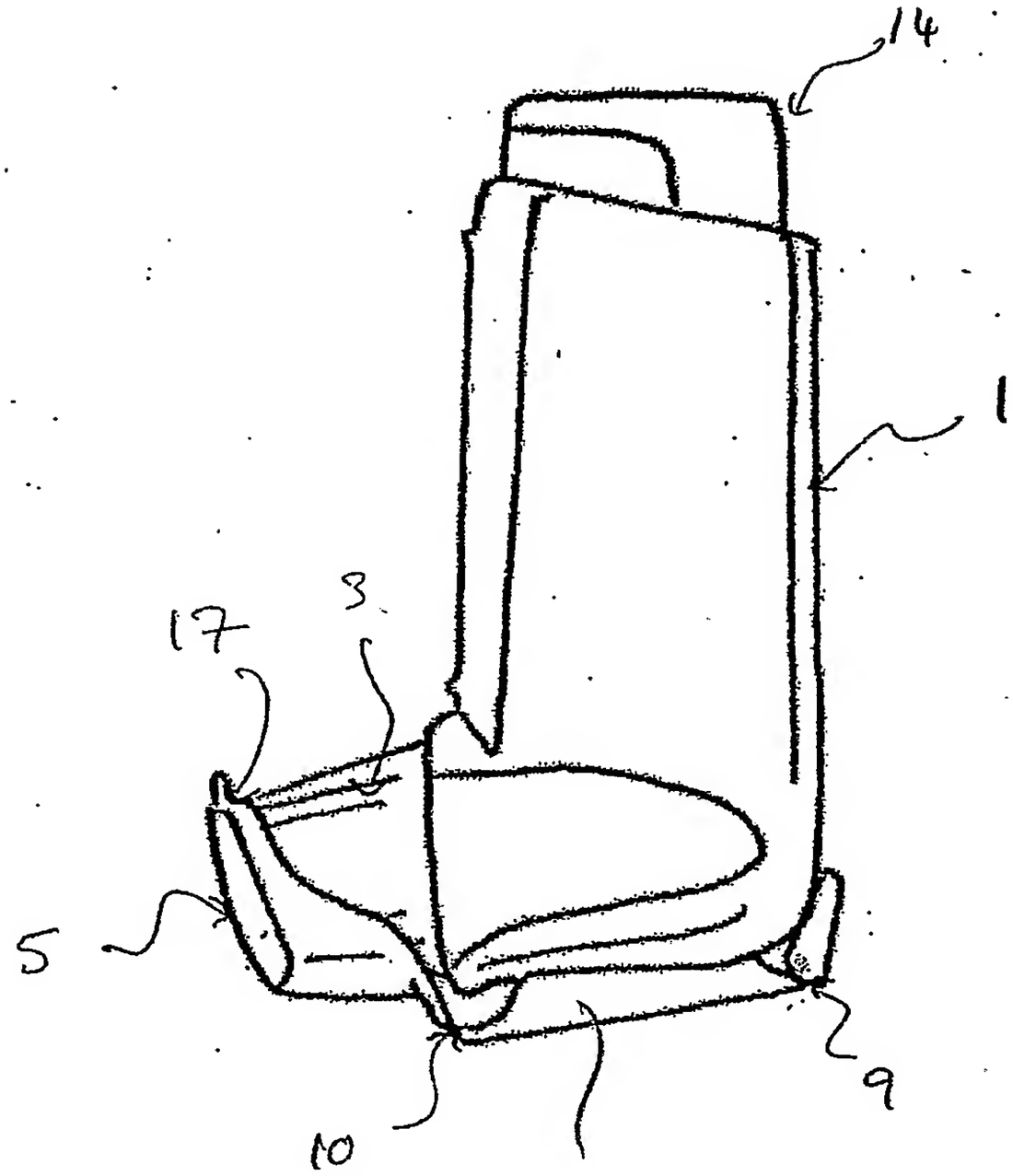




FIG. 5

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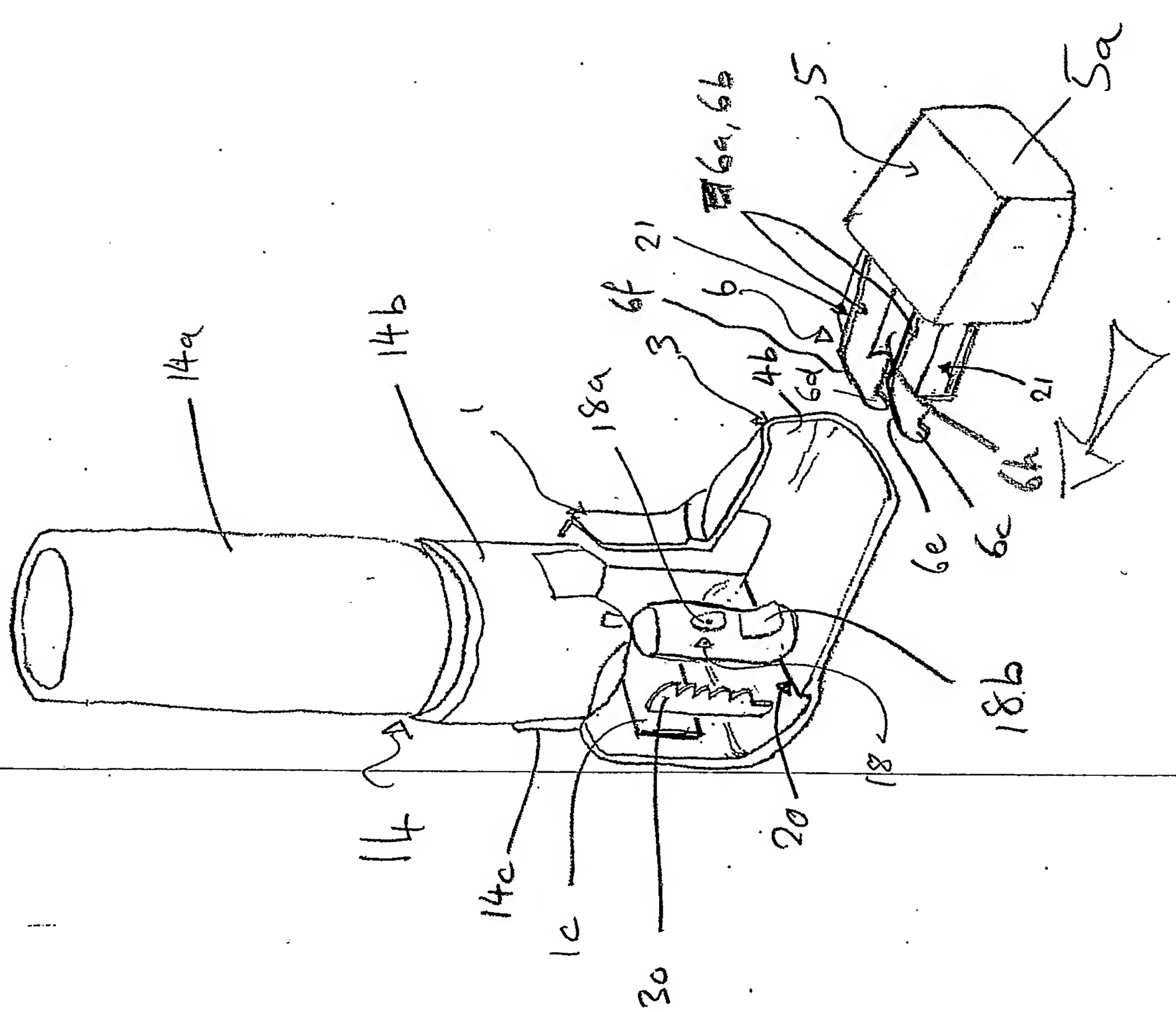

14a
14b
1
18a
3
6f
2'
6
6a, 6b
5
5a
46
6d
21
6e
6c
6h
18b
18
14
14c
1c
30
20

FIG 6

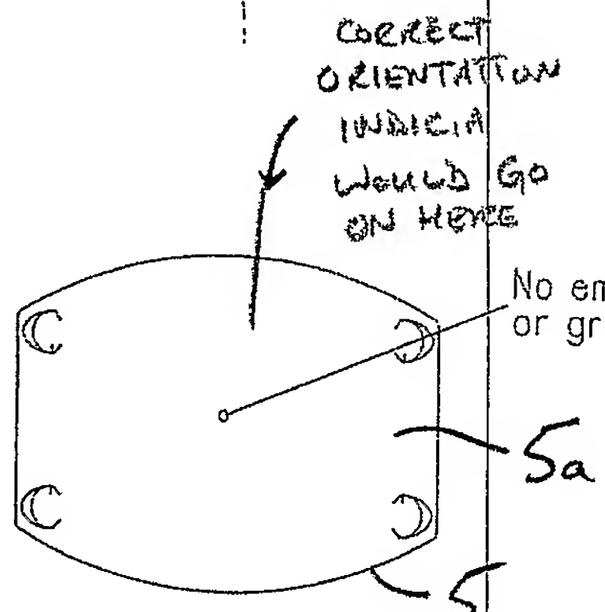



FIG. 6E

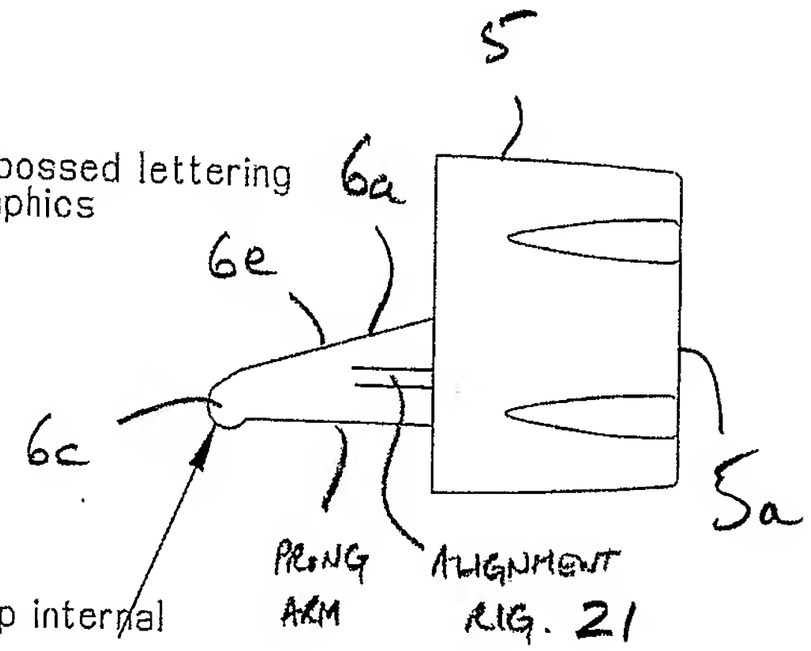



FIG. 6D

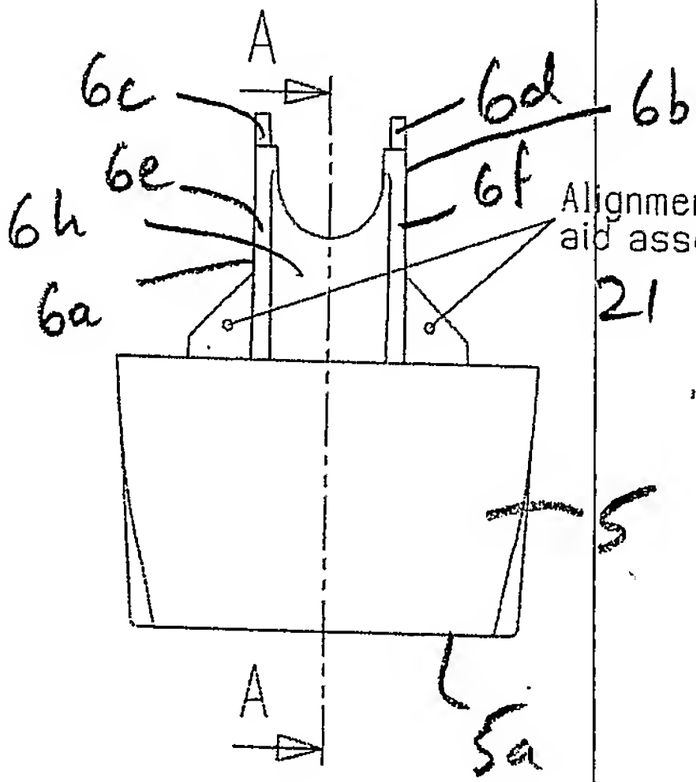



FIG. 6B

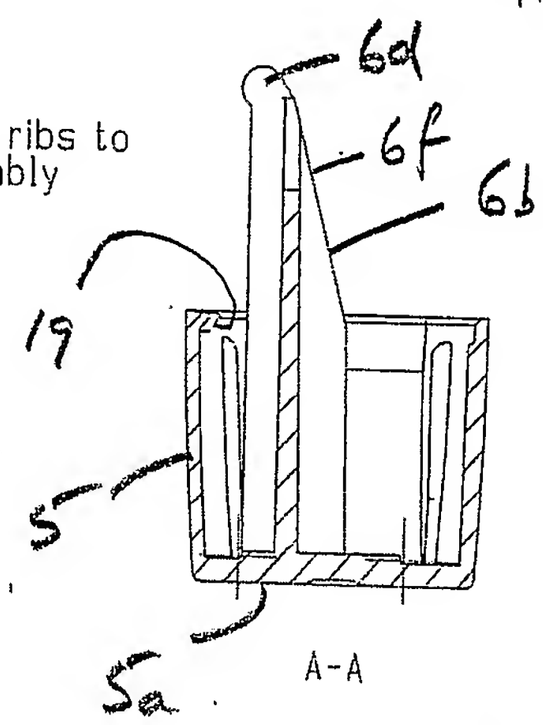



FIG. 6C

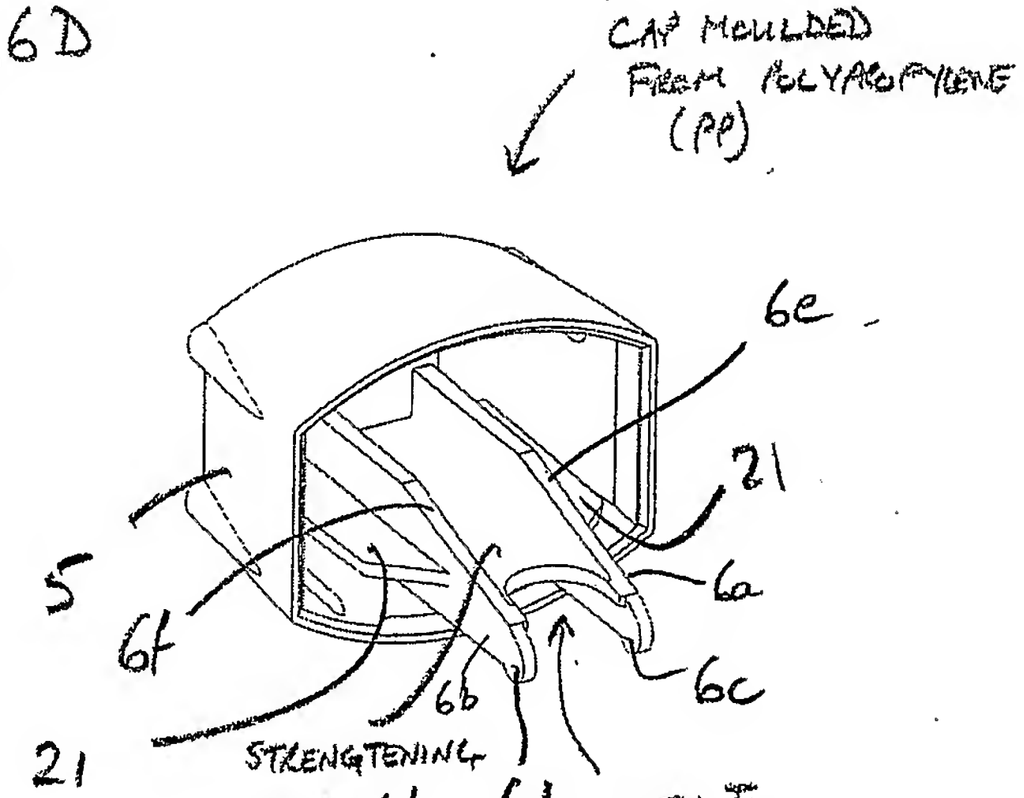
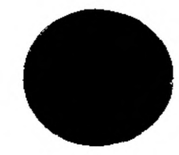
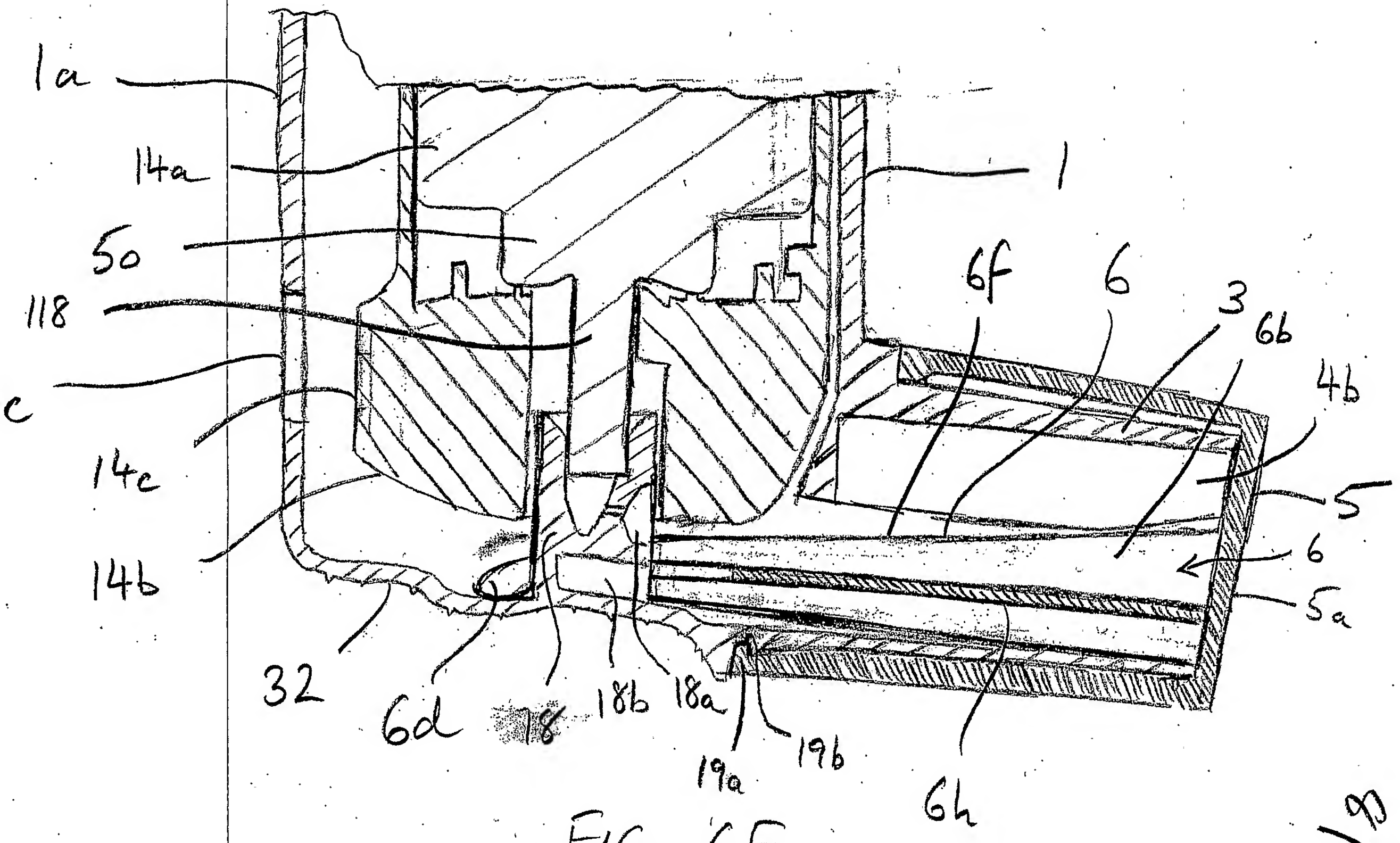



FIG. 6A




1a
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118
1c
14c
14b
32
6d
18
18b
18a
19a
19b
6h
1
6f
6
3
6b
4b
5
6
5a

FIG. 6F

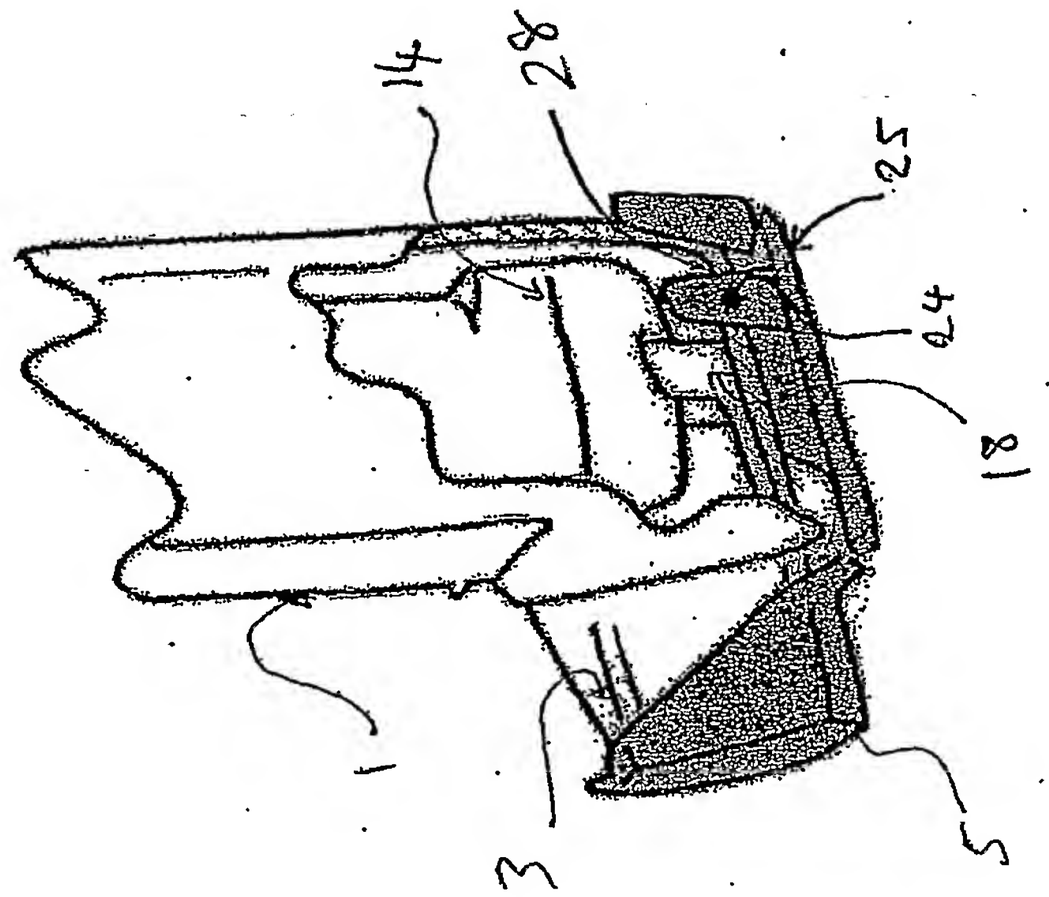


FIG 7B

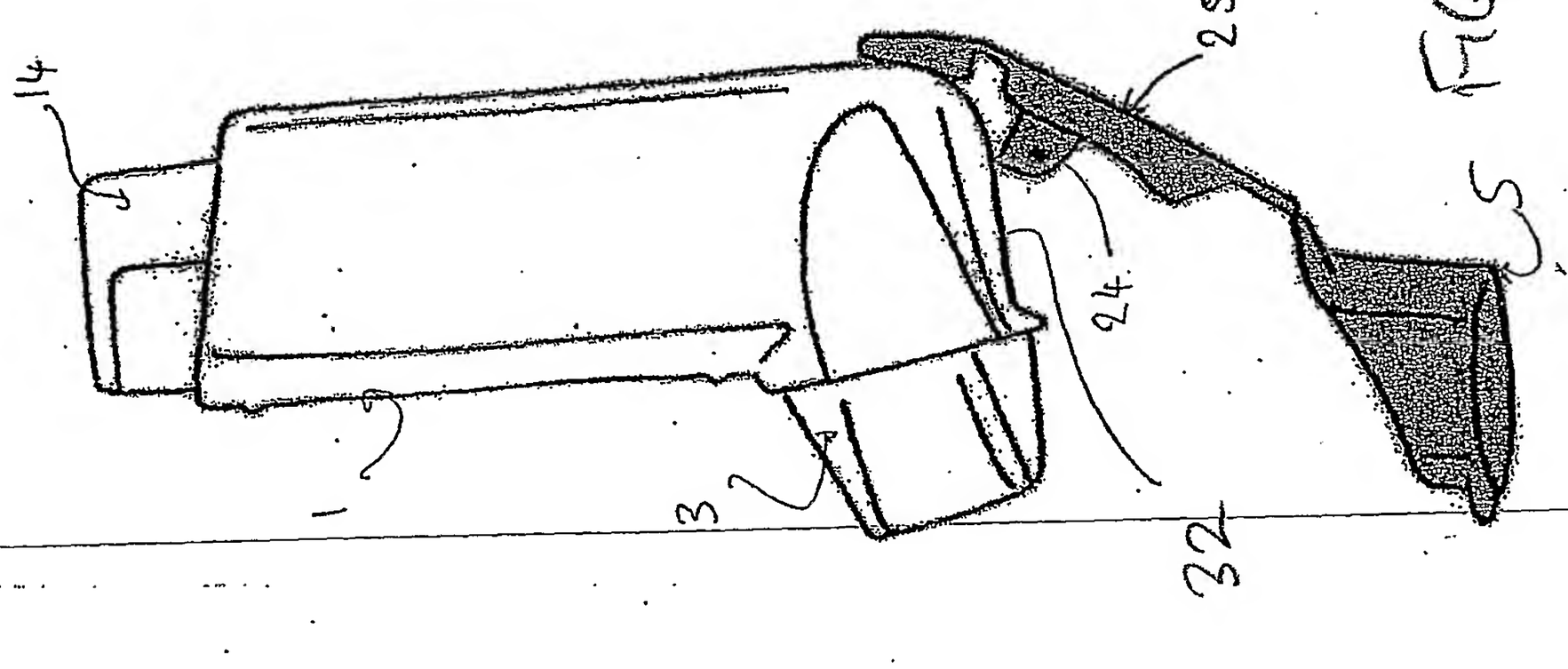


FIG 7A

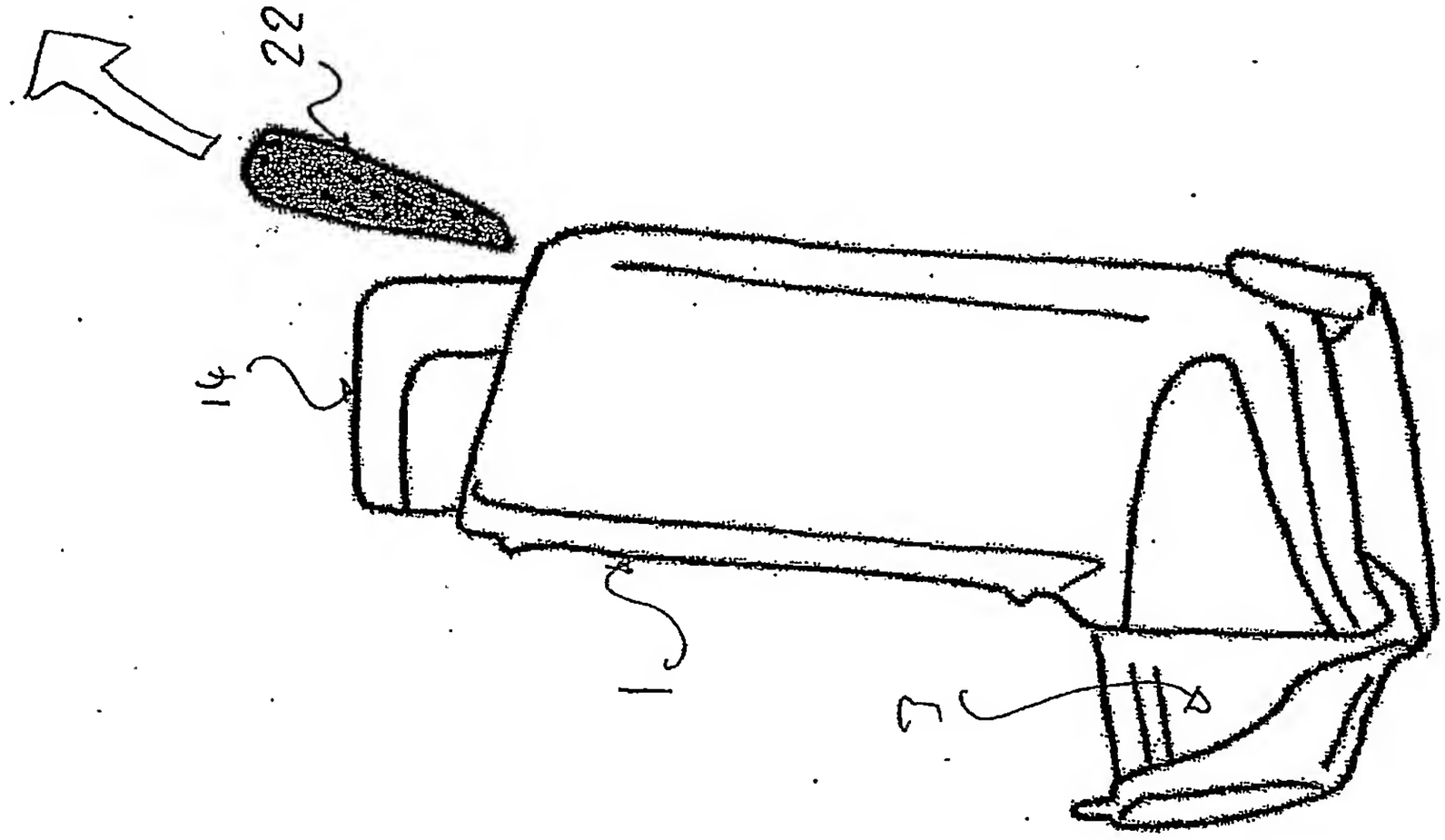


FIG. 8B

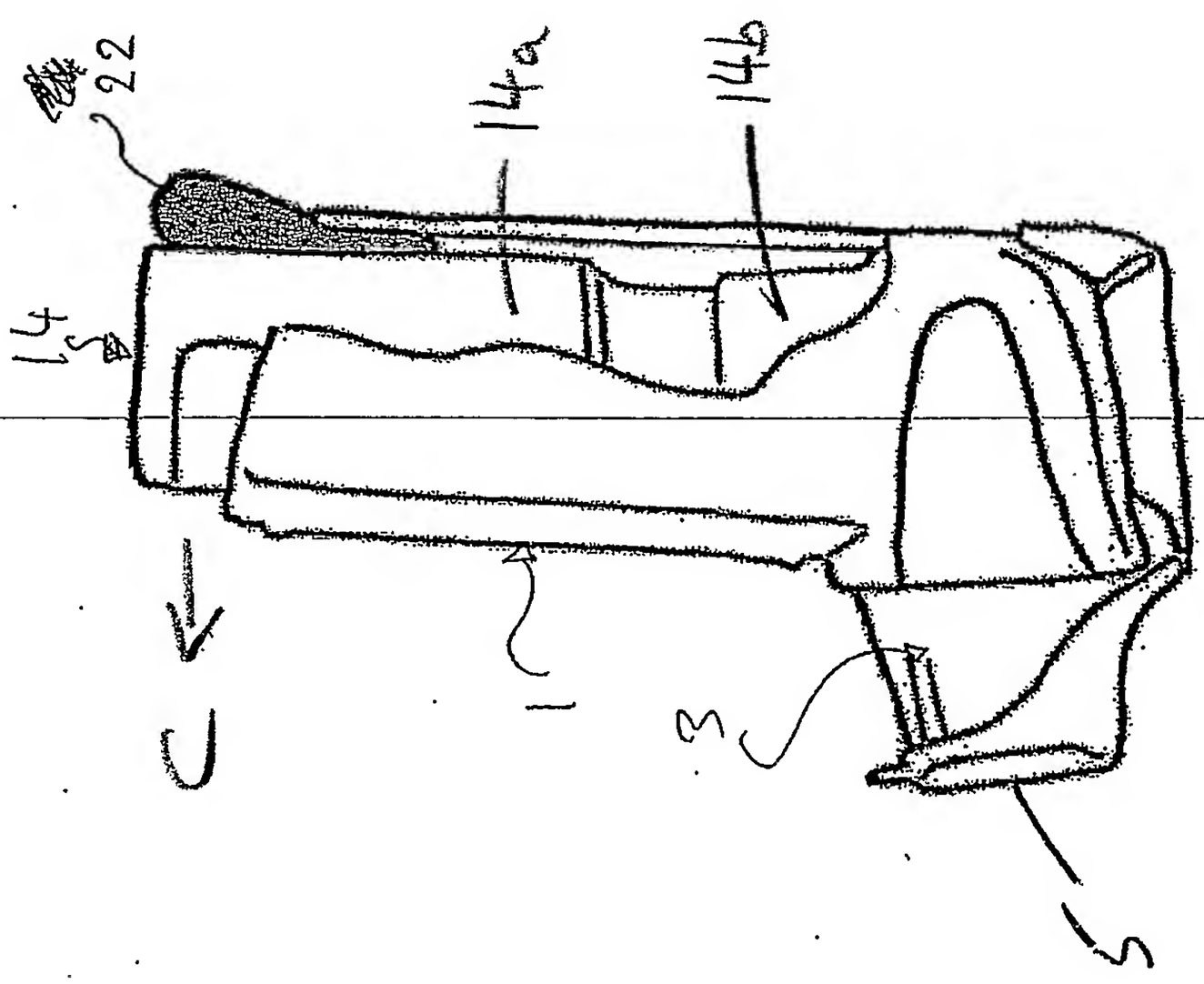


FIG. 8A

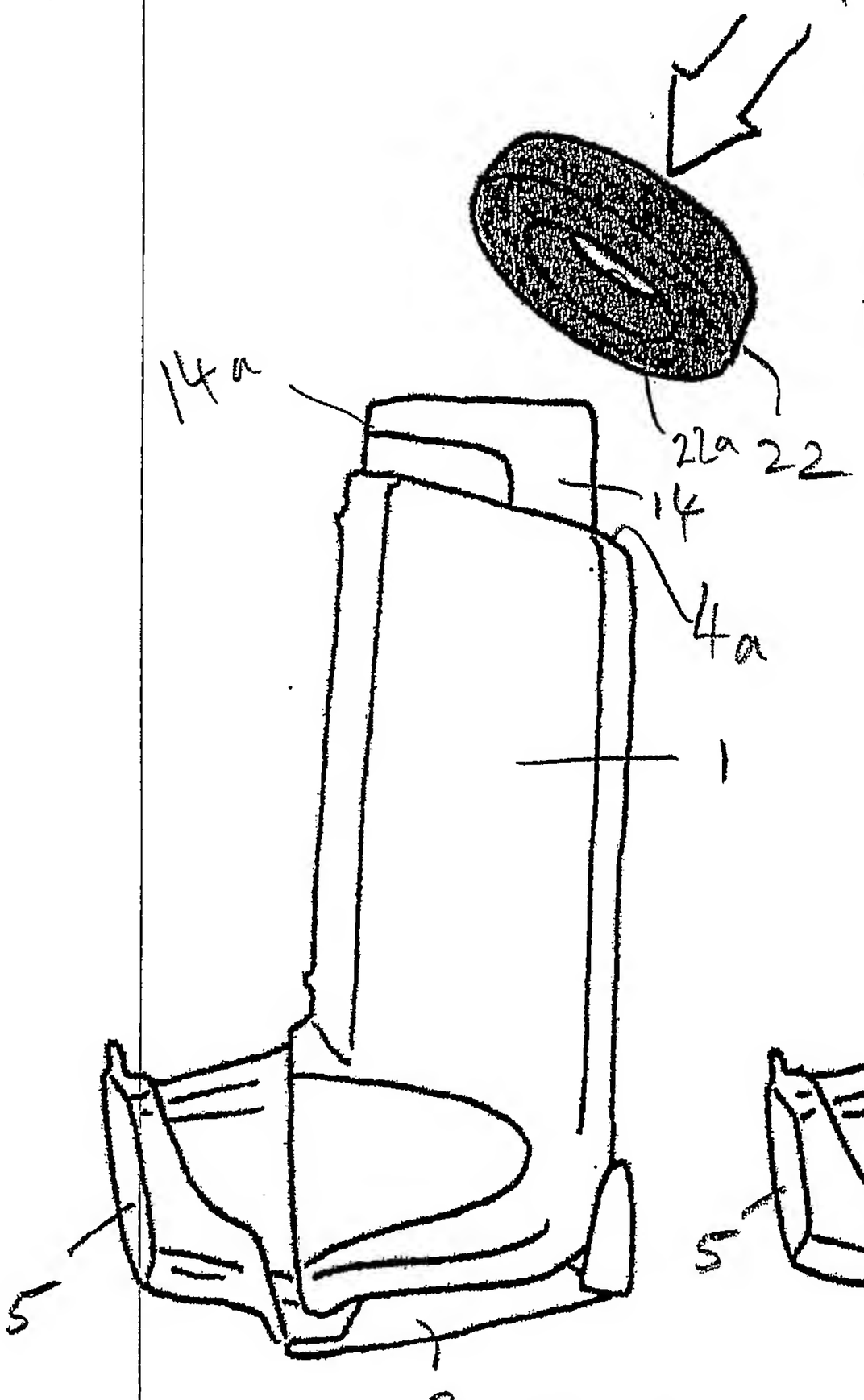


FIG. 9A

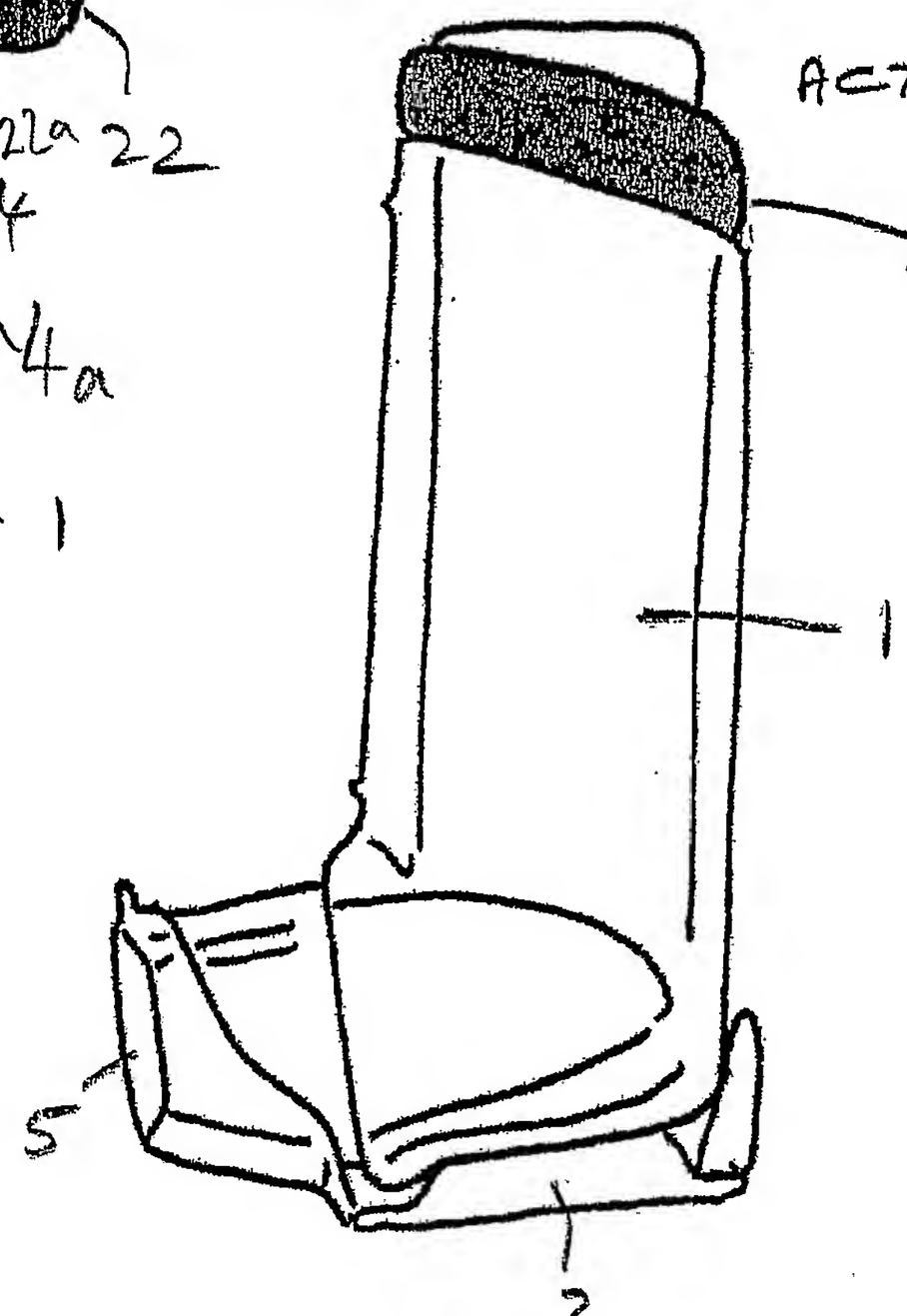


FIG. 9B

FOAM COLLAR OVER CAM PROVIDES DAMPING OF MOVEMENT BETWEEN CAM AND ACTUATOR

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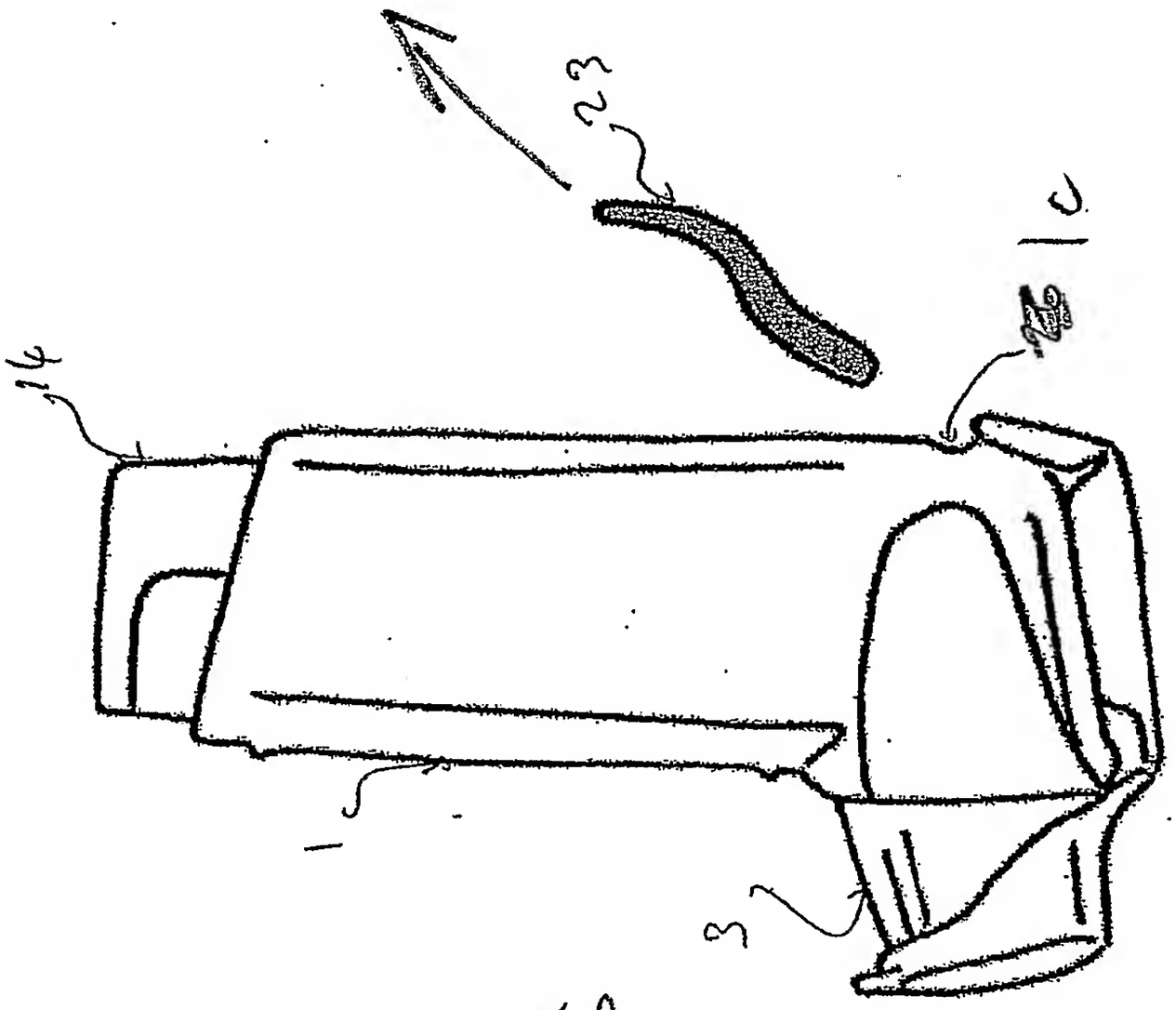


FIG. 10B

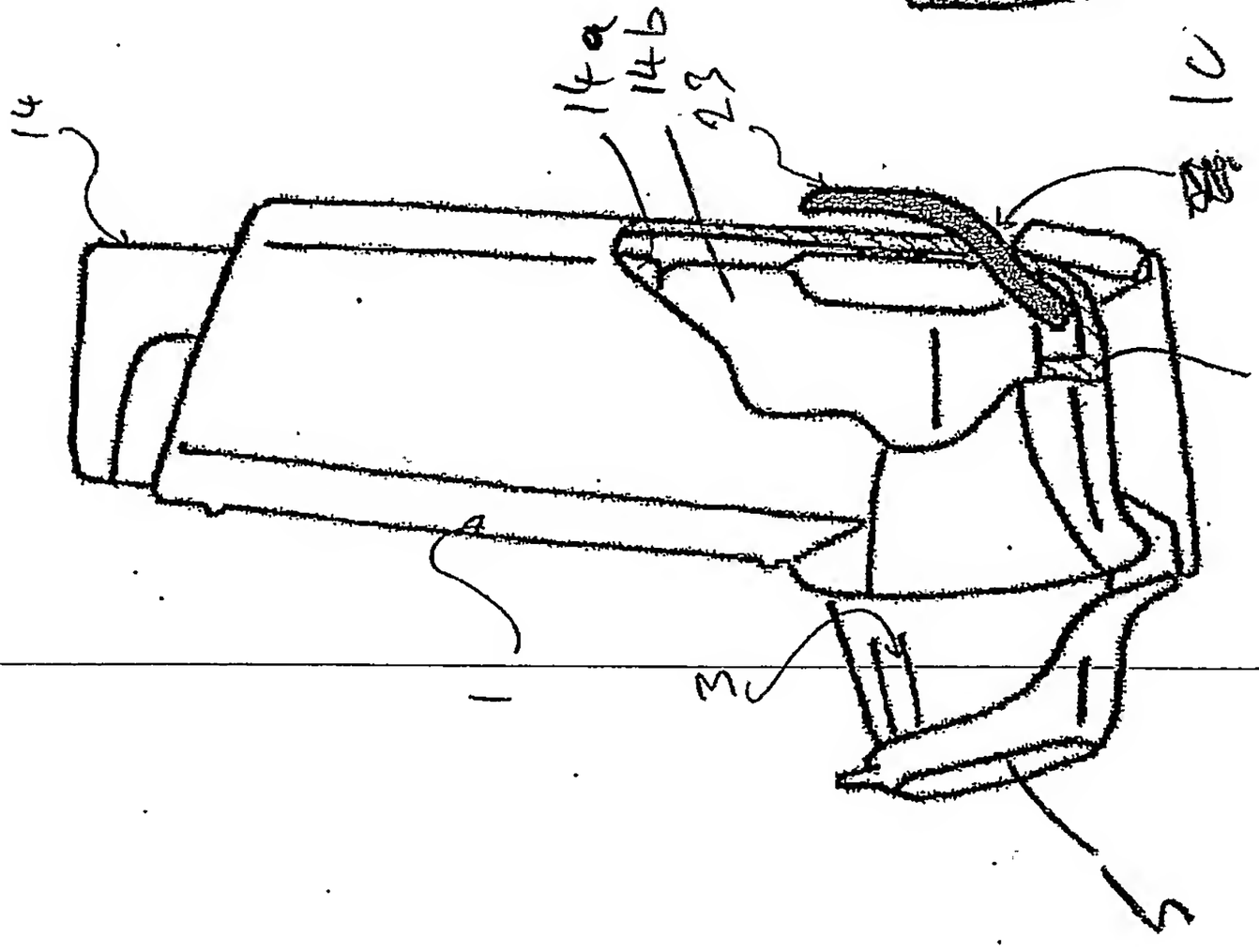


FIG. 10A

TAPE APPLIED TO ACTUATOR IS DRESSED THROUGH WINDOW OPENING ONTO COUNTER WINDOW

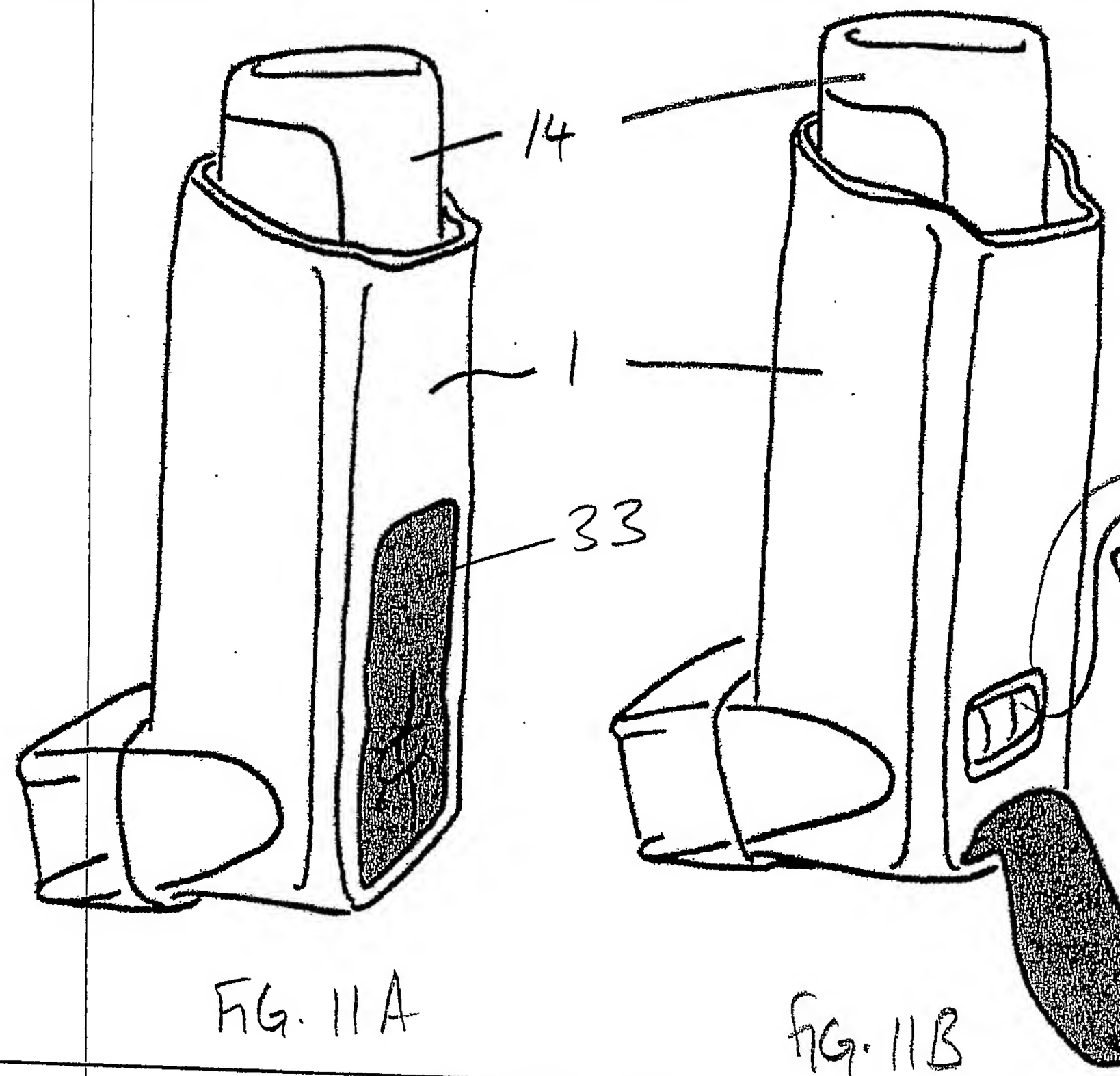


FIG. 11A




FIG. 11B

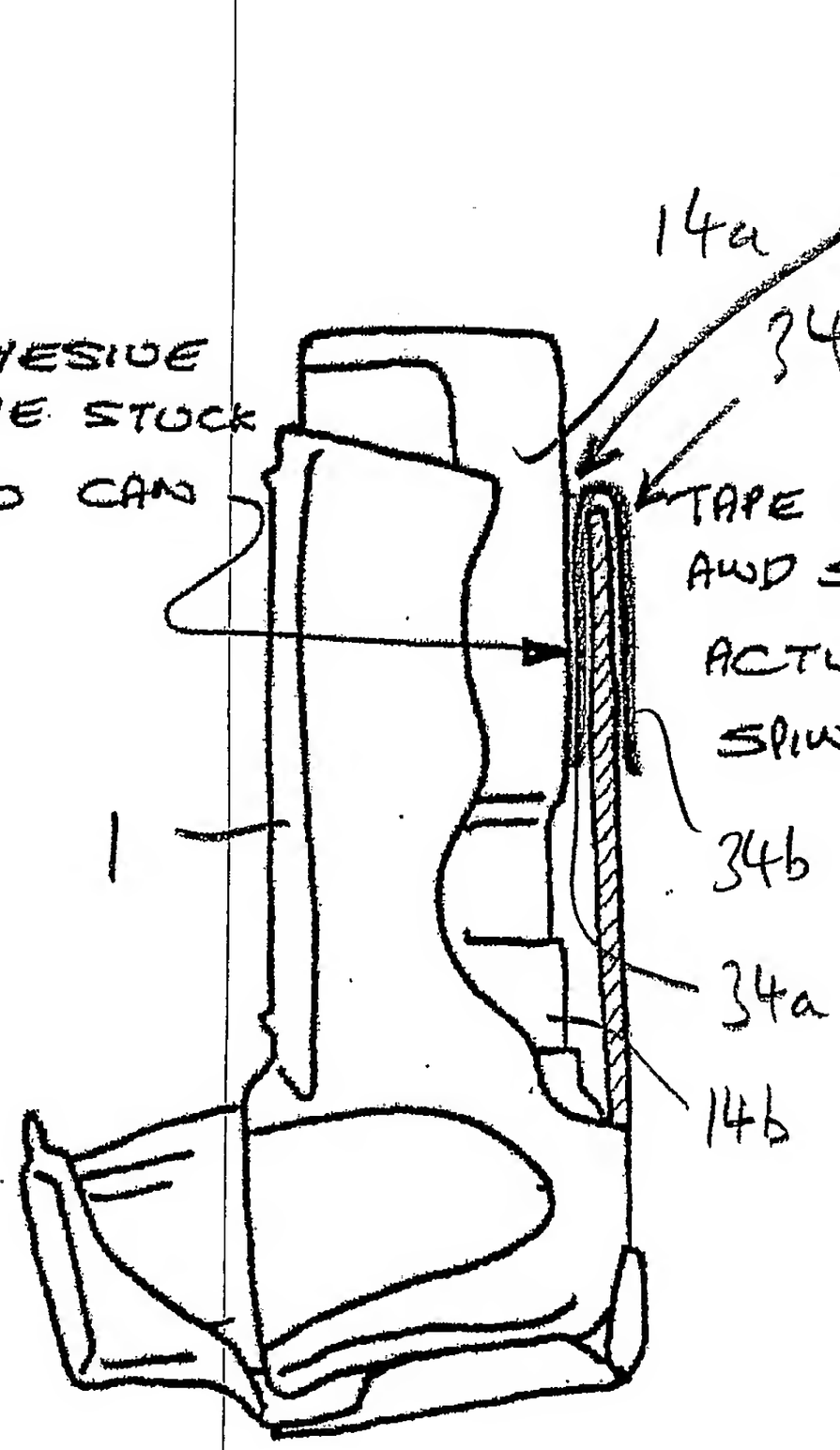


FIG. 12A

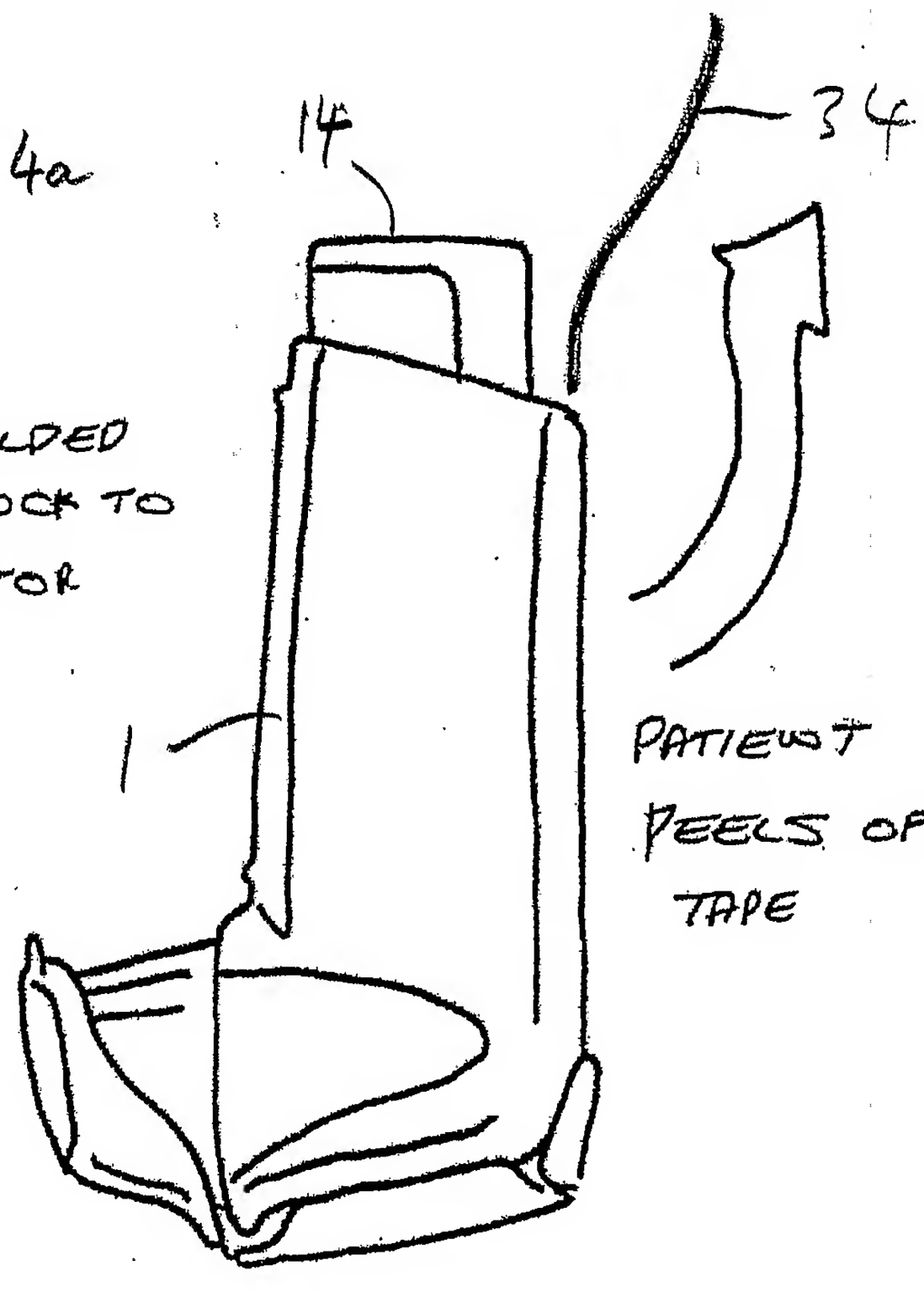


FIG. 12B

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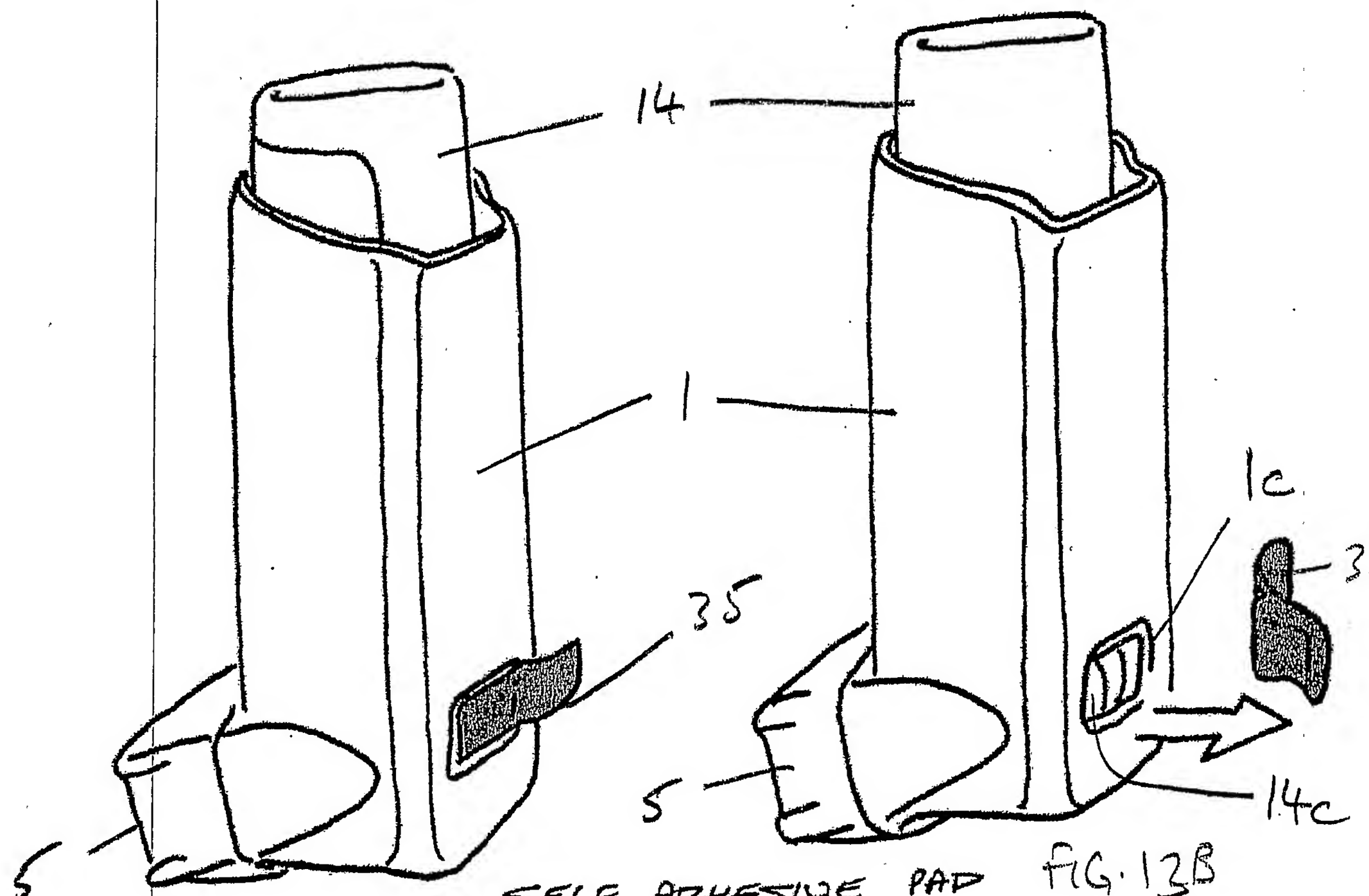


FIG. 13A

FIG. 13B

SELF ADHESIVE PAD STUCK TO COUNTER WINDOW THROUGH THE ACTUATOR HOLE.

VACUUM FORMED PRESS FIT CAP ISOLATES MOVEMENT BETWEEN CAM AND ACTUATOR

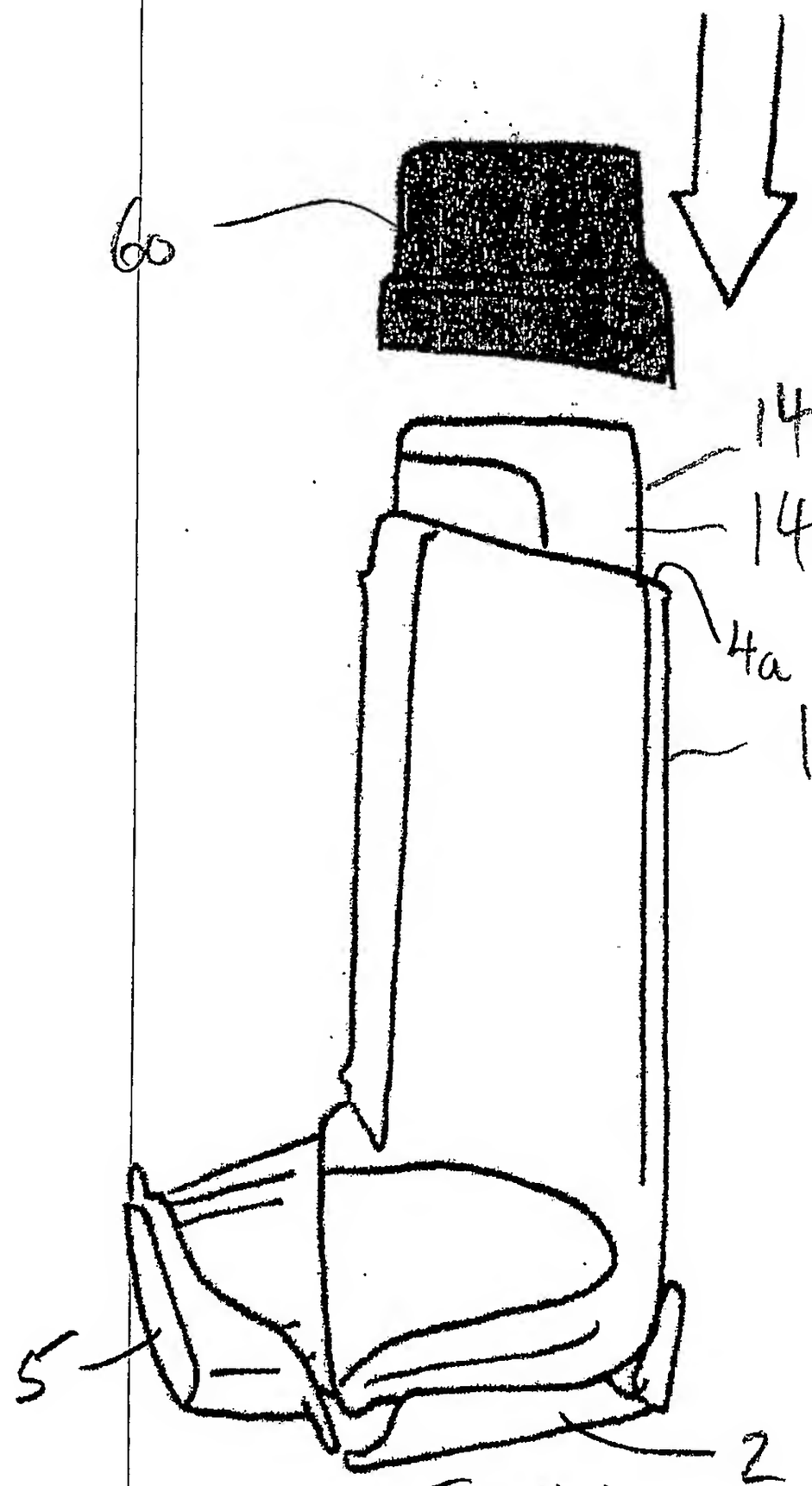


FIG. 14A

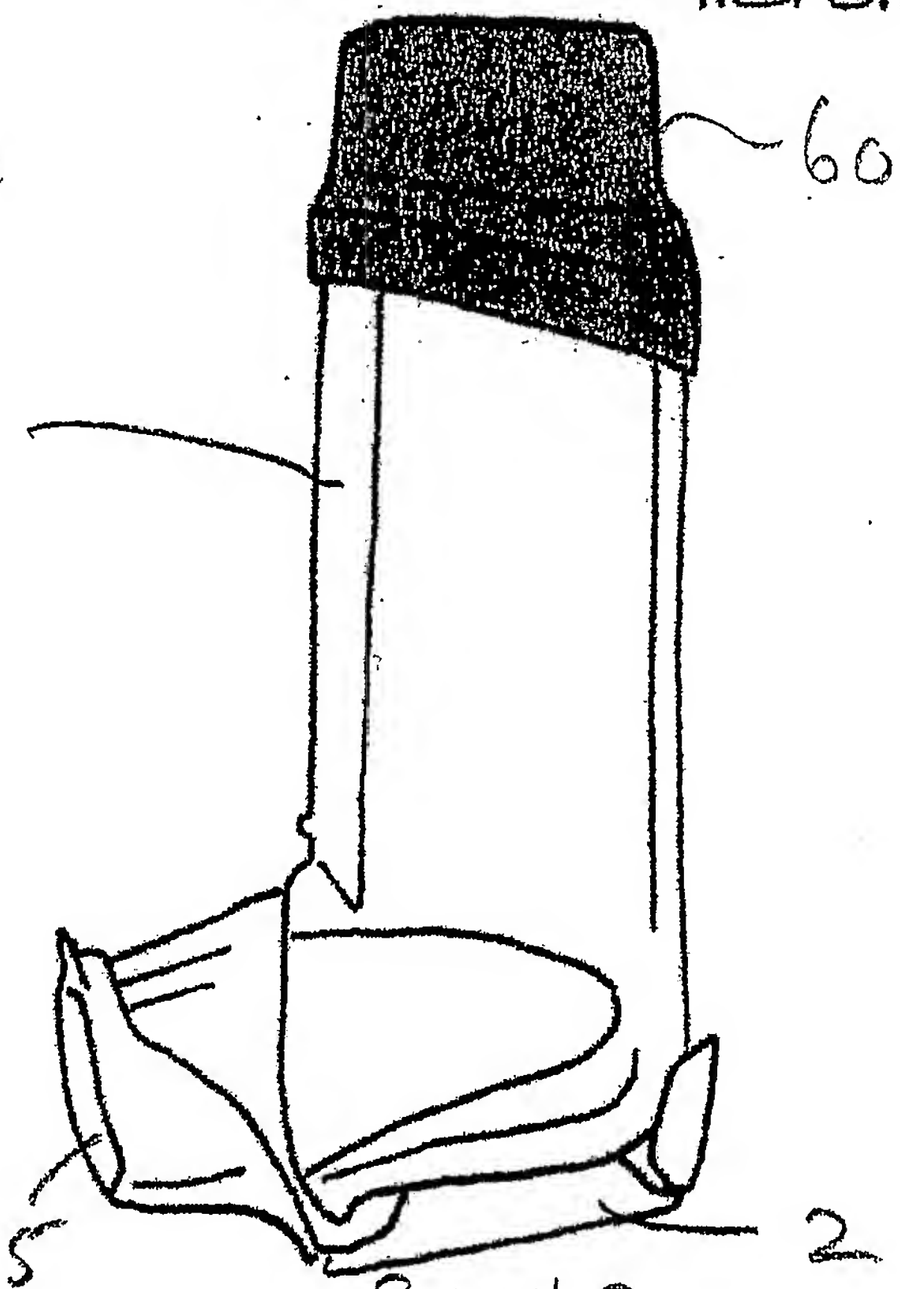


FIG. 14B

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